# **EXHIBIT J**

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FOR THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC.,
PELVIC REPAIR SYSTEMS
PRODUCTS LIABILITY LITIGATION
Master File No. 2:12-MD-02327
MDL NO. 2327

THIS DOCUMENT RELATES TO:

TONYA AND GARY EDWARDS vs.
ETHICON, INC., ET AL.,
(Case No. 2:12-cv-09972)

JOSEPH R. GOODWIN
U.S. DISTRICT
JUDGE

and

JO HUSKEY AND ALLEN HUSKEY vs.
ETHICON, INC., ET AL.,
(Case No. 2:12-cv-05201)

DEPOSITION OF SCOTT A. GUELCHER, PH.D.

Nashville, Tennessee

March 25, 2014

Reported by Marilyn Morgan, LCR #235, CCR #0174

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1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	APPEARANCES: ON BEHALF OF PLAINTIFFS Tim E. Jackson, Esq. Michael H. Bowman, Esq. WEXLER WALLACE, LLP 55 West Monroe Street, Suite 3300 Chicago, Illinois 60603 (312) 346-2222 tej@wexlerwallace.com mhb@wexlerwallace.com and Christina Lewis, Esq. (by telephone) MUELLER LAW 404 West 7th Street Austin, Texas 78701 (512) 478-1236 ON BEHALF OF DEFENDANT: David B. Thomas, Esq. THOMAS, COMBS & SPANN, PLLC 300 Summers Street, Suite 1380 Charleston, West Virginia 25338 (304) 414-1807 dthomas@tcspllc.com	1
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	The deposition of SCOTT A. GUELCHER, PH.D., taken on behalf of the Defendant and taken pursuant to notice on March 25, 2014, beginning at approximately 9:19 a.m., at 150 3rd Avenue, South, Nashville, Tennessee, pursuant to stipulations of counsel.  STIPULATIONS  It is agreed that the court reporter, being a notary public for the State of Tennessee, may swear the deponent, take the deposition on the Stenograph shorthand machine and afterwards reduce the same to typewriting when it may be used for all purposes provided by the Federal Rules of Civil Procedure governing depositions.	Page 5  SCOTT A. GUELCHER, PH.D., after having been first duly sworn, was examined and testified as follows:  DIRECT EXAMINATION BY MR. THOMAS: Q. Good morning, Dr. Guelcher. It's Guelcher; is that correct? A. That's right. Q. I introduced myself to you before the deposition. My name is David Thomas. I represent Ethicon. I'm going to ask you a number of questions today about your expert reports in the Ethicon matters; fair enough? A. Yes. Q. I see that you have before you two notebooks. What's in the notebooks? A. So one of these notebooks is the report with the first report that was filed with the reliance documents from that. And the second notebook is another notebook of support documents. Q. We'll both be doing that today so take your time and don't worry about it. The second notebook that you referred

1 2 3 4 5 6	to is additional support documents?  A. Yes, that's right.	1	A. Yes.
3 4 5 6	=	۱ ،	
4 5 6	O D (1 11'(' 1 / 1 / 1	2	MR. THOMAS: We'll mark that as
5 6	Q. Do the additional support documents	3	Exhibit No. 2.
6	in the second notebook relate to the first	4	(Exhibit 2 was marked.)
	report?	5	Q. (By Mr. Thomas) This was the first
7	A. Yes.	6	notebook to which you referred for your expert
7	Q. Do the two notebooks that you have in	7	report and your reliance materials; fair?
8	front of you represent the total of the	8	A. Yes.
9	reliance materials for the reports that you've	9	(Exhibit 3 was marked.)
10	provided in this matter?	10	Q. (By Mr. Thomas) Deposition Exhibit
11	A. Yes.	11	No. 3 is a second notebook of documents that
12	(Exhibit 1 was marked.)	12	you brought with you that are your reliance
13	Q. (By Mr. Thomas) Let me show you what	13	materials for your expert report in the Ethicon
14	I've marked as deposition Exhibit No. 1.	14	case?
15	Deposition Exhibit No. 1 is what was provided	15	A. Yes.
16	to us as the Rule 26 expert report for you in	16	Q. It's your testimony that the
17	this matter.	17	documents in Exhibits 2 and 3 are the total of
18	When you referred to your first	18	the reliance materials for your expert report
19	notebook as having the report and reliance	19	which we've marked as Exhibit 1?
20	materials, is Exhibit No. 1 the report to which	20	A. Yes.
21	you're referring?	21	Q. All right. Did you bring with you
22	A. Yes.	22	any other materials for your deposition today?
23	Q. On at the end I'm sorry.	23	A. No.
24	Exhibit B to Exhibit No. 1 is a list of	24	Q. Did you bring any billing records
	Page 7		Page 9
1	reliance materials attached to your report?	1	with you today?
2	A. Yes.	2	A. No. Dr. Dunn has those. That's
3	Q. Do you have that?	3	subcontracted through Dr. Dunn.
4	A. Yes.	4	Q. Did you prepare billing records that
5	Q. Is everything that is in the two	5	you gave to Dr. Dunn?
6	notebooks that you've just identified for the	6	A. I have sent him some billing records,
7	record contained within the reliance materials,	7	yeah. But I don't have those with me.
8	to your knowledge?	8	Dr. Dunn has them.
9	A. Yes, I believe so.	9	Q. Is there a reason why you didn't
10	Q. Are there documents in this reliance	10	bring those with you here today?
11	list that are not contained in the two	11	A. I haven't been bringing them to
12	notebooks that you brought with you today?	12	depositions. So everything is billed through
13	A. I don't think so.	13	him. So I don't have them with me.
14	Q. Okay. Was it your intention when you	14	MR. THOMAS: Is there a reason why he
15	brought the two notebooks that you've	15	hasn't produced those today?
16	identified earlier today that you brought with	16	MR. JACKSON: It was my understanding
17	you all the documents upon which you relied for	17	he didn't have them, that they were all in
18	the formulation of your opinions in the case?	18	the custody of Dr. Dunn.
19	A. Yes.	19	(Exhibit 4 was marked.)
20	Q. Just for the record, the first	20	Q. (By Mr. Thomas) Let me show you
21	notebook that you identified it has a title on	21	what's been marked as deposition Exhibit No. 4.
22	it that says In Re: Boston Scientific	22	Deposition Exhibit No. 4 is a notice of your
2.2	Corporation, Product Liability Litigation,	23	deposition for today as well as a document
23	Expert Report of Scott Guelcher, Ph.D.	24	rider that requests that you bring certain

	Page 10		Page 12
1	documents with you to the deposition. Did you	1	Q. Do you have notes of the time that
2	review that in advance of your deposition?	2	you spent that you transfer over to Microsoft
3	A. Briefly.	3	Word?
4	Q. What did you do when you reviewed it?	4	A. I keep it on my calendar.
5	For what purpose did you review it?	5	Q. And is your calendar a hard copy
6	A. To pull the documents together.	6	calendar?
7	Q. And I believe you've told me the only	7	A. It's electronic on my phone.
8	documents that you've brought with you to the	8	Q. And the time that you have on your
9	deposition today are the ones that we've marked	9	electronic calendar on your phone is
10	in the notebooks of Exhibits Nos. 2 and 3?	10	transferred over to your Microsoft Word report
11	A. That's right.	11	that you send to Dr. Dunn on a weekly basis?
12	Q. Were there other documents that are	12	A. That's right. Yes.
13	responsive to Schedule A on Exhibit No. 4 that	13	Q. And the report that you provide to
14	you didn't bring with you?	14	Dr. Dunn identifies the day that you worked?
15	MR. JACKSON: I'm just going to note	15	A. It identifies the day, the time of
16	that we have pending objections to several	16	day, and the number of hours and the activity.
17	of these scheduling requests.	17	Q. Is that a form that you prepared or a
18	MR. THOMAS: That's fine.	18	form that Dr. Dunn provided to you?
19	A. Let me look at this for a minute.	19	A. It's a form that I had from other
20	So I have provided an opinion on	20	cases, other consulting, I should say.
21	other pelvic mesh cases, but I did not bring	21	Q. Other consulting with Dr. Dunn or
22	that information with me because of the	22	consulting you've done individually?
23	consulting with the attorneys. I think	23	A. Consulting I've done individually
24	everything else is here, just looking at this.	24	with other companies.
	Page 11		Page 13
1	Q. (By Mr. Thomas) Let's look at	1	Q. Are the weekly activity reports that
2	Q. (By Mr. Thomas) Let's look at Paragraph 1 of Exhibit 1, Schedule A, all	2	Q. Are the weekly activity reports that you submitted to Dr. Dunn on your computer
2 3	Q. (By Mr. Thomas) Let's look at Paragraph 1 of Exhibit 1, Schedule A, all documents related to fees, billing, and/or time	2 3	Q. Are the weekly activity reports that you submitted to Dr. Dunn on your computer presently?
2 3 4	Q. (By Mr. Thomas) Let's look at Paragraph 1 of Exhibit 1, Schedule A, all documents related to fees, billing, and/or time spent in connection with your opinions.	2 3 4	Q. Are the weekly activity reports that you submitted to Dr. Dunn on your computer presently?  A. I think so. I don't think I deleted
2 3 4 5	Q. (By Mr. Thomas) Let's look at Paragraph 1 of Exhibit 1, Schedule A, all documents related to fees, billing, and/or time spent in connection with your opinions. How do you keep your time in this	2 3 4 5	Q. Are the weekly activity reports that you submitted to Dr. Dunn on your computer presently?  A. I think so. I don't think I deleted those off my computer.
2 3 4 5 6	Q. (By Mr. Thomas) Let's look at Paragraph 1 of Exhibit 1, Schedule A, all documents related to fees, billing, and/or time spent in connection with your opinions.  How do you keep your time in this case?	2 3 4 5 6	Q. Are the weekly activity reports that you submitted to Dr. Dunn on your computer presently?  A. I think so. I don't think I deleted those off my computer.  Q. Is that something you could have sent
2 3 4 5 6 7	Q. (By Mr. Thomas) Let's look at Paragraph 1 of Exhibit 1, Schedule A, all documents related to fees, billing, and/or time spent in connection with your opinions. How do you keep your time in this case? A. I send activity reports to Dr. Dunn,	2 3 4 5 6 7	Q. Are the weekly activity reports that you submitted to Dr. Dunn on your computer presently?  A. I think so. I don't think I deleted those off my computer.  Q. Is that something you could have sent to us today so we could
2 3 4 5 6 7 8	Q. (By Mr. Thomas) Let's look at Paragraph 1 of Exhibit 1, Schedule A, all documents related to fees, billing, and/or time spent in connection with your opinions. How do you keep your time in this case? A. I send activity reports to Dr. Dunn, and then he I must have misunderstood this.	2 3 4 5 6 7 8	Q. Are the weekly activity reports that you submitted to Dr. Dunn on your computer presently?  A. I think so. I don't think I deleted those off my computer.  Q. Is that something you could have sent to us today so we could  A. I can. Like I said, in the past,
2 3 4 5 6 7 8	Q. (By Mr. Thomas) Let's look at Paragraph 1 of Exhibit 1, Schedule A, all documents related to fees, billing, and/or time spent in connection with your opinions.  How do you keep your time in this case?  A. I send activity reports to Dr. Dunn, and then he I must have misunderstood this. It's all billed through Dr. Dunn's company. So	2 3 4 5 6 7 8	Q. Are the weekly activity reports that you submitted to Dr. Dunn on your computer presently?  A. I think so. I don't think I deleted those off my computer.  Q. Is that something you could have sent to us today so we could  A. I can. Like I said, in the past, I've not Dr. Dunn just had those, and I just
2 3 4 5 6 7 8 9	Q. (By Mr. Thomas) Let's look at Paragraph 1 of Exhibit 1, Schedule A, all documents related to fees, billing, and/or time spent in connection with your opinions. How do you keep your time in this case? A. I send activity reports to Dr. Dunn, and then he I must have misunderstood this. It's all billed through Dr. Dunn's company. So I send everything to him in the form of weekly	2 3 4 5 6 7 8 9	Q. Are the weekly activity reports that you submitted to Dr. Dunn on your computer presently?  A. I think so. I don't think I deleted those off my computer.  Q. Is that something you could have sent to us today so we could  A. I can. Like I said, in the past, I've not Dr. Dunn just had those, and I just missed it.
2 3 4 5 6 7 8 9 10	Q. (By Mr. Thomas) Let's look at Paragraph 1 of Exhibit 1, Schedule A, all documents related to fees, billing, and/or time spent in connection with your opinions. How do you keep your time in this case? A. I send activity reports to Dr. Dunn, and then he I must have misunderstood this. It's all billed through Dr. Dunn's company. So I send everything to him in the form of weekly activity reports and monthly invoices.	2 3 4 5 6 7 8 9 10 11	Q. Are the weekly activity reports that you submitted to Dr. Dunn on your computer presently?  A. I think so. I don't think I deleted those off my computer.  Q. Is that something you could have sent to us today so we could  A. I can. Like I said, in the past, I've not Dr. Dunn just had those, and I just missed it.  Q. Okay.
2 3 4 5 6 7 8 9 10 11 12	Q. (By Mr. Thomas) Let's look at Paragraph 1 of Exhibit 1, Schedule A, all documents related to fees, billing, and/or time spent in connection with your opinions.  How do you keep your time in this case?  A. I send activity reports to Dr. Dunn, and then he I must have misunderstood this. It's all billed through Dr. Dunn's company. So I send everything to him in the form of weekly activity reports and monthly invoices.  Q. Tell me the form that the weekly	2 3 4 5 6 7 8 9 10 11 12	Q. Are the weekly activity reports that you submitted to Dr. Dunn on your computer presently?  A. I think so. I don't think I deleted those off my computer.  Q. Is that something you could have sent to us today so we could  A. I can. Like I said, in the past, I've not Dr. Dunn just had those, and I just missed it.  Q. Okay.  A. I can send them to you.
2 3 4 5 6 7 8 9 10 11 12 13	Q. (By Mr. Thomas) Let's look at Paragraph 1 of Exhibit 1, Schedule A, all documents related to fees, billing, and/or time spent in connection with your opinions.  How do you keep your time in this case?  A. I send activity reports to Dr. Dunn, and then he I must have misunderstood this. It's all billed through Dr. Dunn's company. So I send everything to him in the form of weekly activity reports and monthly invoices.  Q. Tell me the form that the weekly activity reports take.	2 3 4 5 6 7 8 9 10 11 12 13	Q. Are the weekly activity reports that you submitted to Dr. Dunn on your computer presently?  A. I think so. I don't think I deleted those off my computer.  Q. Is that something you could have sent to us today so we could  A. I can. Like I said, in the past, I've not Dr. Dunn just had those, and I just missed it.  Q. Okay.  A. I can send them to you.  Q. Yeah. I would like to be able to ask
2 3 4 5 6 7 8 9 10 11 12 13 14	Q. (By Mr. Thomas) Let's look at Paragraph 1 of Exhibit 1, Schedule A, all documents related to fees, billing, and/or time spent in connection with your opinions.  How do you keep your time in this case?  A. I send activity reports to Dr. Dunn, and then he I must have misunderstood this. It's all billed through Dr. Dunn's company. So I send everything to him in the form of weekly activity reports and monthly invoices.  Q. Tell me the form that the weekly activity reports take.  A. It's a table that lists the hours	2 3 4 5 6 7 8 9 10 11 12 13 14	Q. Are the weekly activity reports that you submitted to Dr. Dunn on your computer presently?  A. I think so. I don't think I deleted those off my computer.  Q. Is that something you could have sent to us today so we could  A. I can. Like I said, in the past, I've not Dr. Dunn just had those, and I just missed it.  Q. Okay.  A. I can send them to you.  Q. Yeah. I would like to be able to ask questions about those today. So to the extent
2 3 4 5 6 7 8 9 10 11 12 13 14	Q. (By Mr. Thomas) Let's look at Paragraph 1 of Exhibit 1, Schedule A, all documents related to fees, billing, and/or time spent in connection with your opinions. How do you keep your time in this case? A. I send activity reports to Dr. Dunn, and then he I must have misunderstood this. It's all billed through Dr. Dunn's company. So I send everything to him in the form of weekly activity reports and monthly invoices. Q. Tell me the form that the weekly activity reports take. A. It's a table that lists the hours that I worked per day, the specific time of the	2 3 4 5 6 7 8 9 10 11 12 13 14 15	Q. Are the weekly activity reports that you submitted to Dr. Dunn on your computer presently?  A. I think so. I don't think I deleted those off my computer.  Q. Is that something you could have sent to us today so we could  A. I can. Like I said, in the past, I've not Dr. Dunn just had those, and I just missed it.  Q. Okay.  A. I can send them to you.  Q. Yeah. I would like to be able to ask questions about those today. So to the extent we can get those sent over here and printed out
2 3 4 5 6 7 8 9 10 11 12 13 14 15	Q. (By Mr. Thomas) Let's look at Paragraph 1 of Exhibit 1, Schedule A, all documents related to fees, billing, and/or time spent in connection with your opinions. How do you keep your time in this case?  A. I send activity reports to Dr. Dunn, and then he I must have misunderstood this. It's all billed through Dr. Dunn's company. So I send everything to him in the form of weekly activity reports and monthly invoices. Q. Tell me the form that the weekly activity reports take. A. It's a table that lists the hours that I worked per day, the specific time of the day that I worked on it, and then a brief	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	Q. Are the weekly activity reports that you submitted to Dr. Dunn on your computer presently?  A. I think so. I don't think I deleted those off my computer.  Q. Is that something you could have sent to us today so we could  A. I can. Like I said, in the past, I've not Dr. Dunn just had those, and I just missed it.  Q. Okay.  A. I can send them to you.  Q. Yeah. I would like to be able to ask questions about those today. So to the extent we can get those sent over here and printed out and used in the deposition
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	Q. (By Mr. Thomas) Let's look at Paragraph 1 of Exhibit 1, Schedule A, all documents related to fees, billing, and/or time spent in connection with your opinions.  How do you keep your time in this case?  A. I send activity reports to Dr. Dunn, and then he I must have misunderstood this. It's all billed through Dr. Dunn's company. So I send everything to him in the form of weekly activity reports and monthly invoices.  Q. Tell me the form that the weekly activity reports take.  A. It's a table that lists the hours that I worked per day, the specific time of the day that I worked on it, and then a brief description of the activity.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	Q. Are the weekly activity reports that you submitted to Dr. Dunn on your computer presently?  A. I think so. I don't think I deleted those off my computer.  Q. Is that something you could have sent to us today so we could  A. I can. Like I said, in the past, I've not Dr. Dunn just had those, and I just missed it.  Q. Okay.  A. I can send them to you.  Q. Yeah. I would like to be able to ask questions about those today. So to the extent we can get those sent over here and printed out and used in the deposition  A. I can do that.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	Q. (By Mr. Thomas) Let's look at Paragraph 1 of Exhibit 1, Schedule A, all documents related to fees, billing, and/or time spent in connection with your opinions.  How do you keep your time in this case?  A. I send activity reports to Dr. Dunn, and then he I must have misunderstood this. It's all billed through Dr. Dunn's company. So I send everything to him in the form of weekly activity reports and monthly invoices.  Q. Tell me the form that the weekly activity reports take.  A. It's a table that lists the hours that I worked per day, the specific time of the day that I worked on it, and then a brief description of the activity.  Q. And is this a report that you submit	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	Q. Are the weekly activity reports that you submitted to Dr. Dunn on your computer presently?  A. I think so. I don't think I deleted those off my computer.  Q. Is that something you could have sent to us today so we could  A. I can. Like I said, in the past, I've not Dr. Dunn just had those, and I just missed it.  Q. Okay.  A. I can send them to you.  Q. Yeah. I would like to be able to ask questions about those today. So to the extent we can get those sent over here and printed out and used in the deposition  A. I can do that.  MR. JACKSON: Do you have somebody
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	Q. (By Mr. Thomas) Let's look at Paragraph 1 of Exhibit 1, Schedule A, all documents related to fees, billing, and/or time spent in connection with your opinions.  How do you keep your time in this case?  A. I send activity reports to Dr. Dunn, and then he I must have misunderstood this. It's all billed through Dr. Dunn's company. So I send everything to him in the form of weekly activity reports and monthly invoices.  Q. Tell me the form that the weekly activity reports take.  A. It's a table that lists the hours that I worked per day, the specific time of the day that I worked on it, and then a brief description of the activity.  Q. And is this a report that you submit to Dr. Dunn on a weekly basis?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	Q. Are the weekly activity reports that you submitted to Dr. Dunn on your computer presently?  A. I think so. I don't think I deleted those off my computer.  Q. Is that something you could have sent to us today so we could  A. I can. Like I said, in the past, I've not Dr. Dunn just had those, and I just missed it.  Q. Okay.  A. I can send them to you.  Q. Yeah. I would like to be able to ask questions about those today. So to the extent we can get those sent over here and printed out and used in the deposition  A. I can do that.  MR. JACKSON: Do you have somebody who can log into your computer and get
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	Q. (By Mr. Thomas) Let's look at Paragraph 1 of Exhibit 1, Schedule A, all documents related to fees, billing, and/or time spent in connection with your opinions.  How do you keep your time in this case?  A. I send activity reports to Dr. Dunn, and then he I must have misunderstood this. It's all billed through Dr. Dunn's company. So I send everything to him in the form of weekly activity reports and monthly invoices.  Q. Tell me the form that the weekly activity reports take.  A. It's a table that lists the hours that I worked per day, the specific time of the day that I worked on it, and then a brief description of the activity.  Q. And is this a report that you submit to Dr. Dunn on a weekly basis?  A. Usually. The reports are all it's	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	Q. Are the weekly activity reports that you submitted to Dr. Dunn on your computer presently?  A. I think so. I don't think I deleted those off my computer.  Q. Is that something you could have sent to us today so we could  A. I can. Like I said, in the past, I've not Dr. Dunn just had those, and I just missed it.  Q. Okay.  A. I can send them to you.  Q. Yeah. I would like to be able to ask questions about those today. So to the extent we can get those sent over here and printed out and used in the deposition  A. I can do that.  MR. JACKSON: Do you have somebody who can log into your computer and get these? It might be easier just to have
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	Q. (By Mr. Thomas) Let's look at Paragraph 1 of Exhibit 1, Schedule A, all documents related to fees, billing, and/or time spent in connection with your opinions.  How do you keep your time in this case?  A. I send activity reports to Dr. Dunn, and then he I must have misunderstood this. It's all billed through Dr. Dunn's company. So I send everything to him in the form of weekly activity reports and monthly invoices.  Q. Tell me the form that the weekly activity reports take.  A. It's a table that lists the hours that I worked per day, the specific time of the day that I worked on it, and then a brief description of the activity.  Q. And is this a report that you submit to Dr. Dunn on a weekly basis?  A. Usually. The reports are all it's a weekly summary.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	Q. Are the weekly activity reports that you submitted to Dr. Dunn on your computer presently?  A. I think so. I don't think I deleted those off my computer.  Q. Is that something you could have sent to us today so we could  A. I can. Like I said, in the past, I've not Dr. Dunn just had those, and I just missed it.  Q. Okay.  A. I can send them to you.  Q. Yeah. I would like to be able to ask questions about those today. So to the extent we can get those sent over here and printed out and used in the deposition  A. I can do that.  MR. JACKSON: Do you have somebody who can log into your computer and get these? It might be easier just to have Dr. Dunn produce everything today. I can
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q. (By Mr. Thomas) Let's look at Paragraph 1 of Exhibit 1, Schedule A, all documents related to fees, billing, and/or time spent in connection with your opinions.  How do you keep your time in this case?  A. I send activity reports to Dr. Dunn, and then he I must have misunderstood this. It's all billed through Dr. Dunn's company. So I send everything to him in the form of weekly activity reports and monthly invoices.  Q. Tell me the form that the weekly activity reports take.  A. It's a table that lists the hours that I worked per day, the specific time of the day that I worked on it, and then a brief description of the activity.  Q. And is this a report that you submit to Dr. Dunn on a weekly basis?  A. Usually. The reports are all it's	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q. Are the weekly activity reports that you submitted to Dr. Dunn on your computer presently?  A. I think so. I don't think I deleted those off my computer.  Q. Is that something you could have sent to us today so we could  A. I can. Like I said, in the past, I've not Dr. Dunn just had those, and I just missed it.  Q. Okay.  A. I can send them to you.  Q. Yeah. I would like to be able to ask questions about those today. So to the extent we can get those sent over here and printed out and used in the deposition  A. I can do that.  MR. JACKSON: Do you have somebody who can log into your computer and get these? It might be easier just to have
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. (By Mr. Thomas) Let's look at Paragraph 1 of Exhibit 1, Schedule A, all documents related to fees, billing, and/or time spent in connection with your opinions.  How do you keep your time in this case?  A. I send activity reports to Dr. Dunn, and then he I must have misunderstood this. It's all billed through Dr. Dunn's company. So I send everything to him in the form of weekly activity reports and monthly invoices.  Q. Tell me the form that the weekly activity reports take.  A. It's a table that lists the hours that I worked per day, the specific time of the day that I worked on it, and then a brief description of the activity.  Q. And is this a report that you submit to Dr. Dunn on a weekly basis?  A. Usually. The reports are all it's a weekly summary.  Q. Is this a computer-generated report	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. Are the weekly activity reports that you submitted to Dr. Dunn on your computer presently?  A. I think so. I don't think I deleted those off my computer.  Q. Is that something you could have sent to us today so we could  A. I can. Like I said, in the past, I've not Dr. Dunn just had those, and I just missed it.  Q. Okay.  A. I can send them to you.  Q. Yeah. I would like to be able to ask questions about those today. So to the extent we can get those sent over here and printed out and used in the deposition  A. I can do that.  MR. JACKSON: Do you have somebody who can log into your computer and get these? It might be easier just to have Dr. Dunn produce everything today. I can probably have them do that.

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1	comfortable for him doing that because he	1	Q. Okay. And then you've consulted with
2	does the actual billing. That's why I was	2	attorneys with respect to Ethicon products?
3	confused. But I think if he can send the	3	A. Yes.
4	reports, it would be better because I don't	4	Q. For a total of three?
5	know that I've I mean, I send them to	5	A. Ethicon would be the fourth product.
6	him and I	6	There are two AMS products.
7	MR. JACKSON: It may be that he was	7	Q. Okay. And have you given deposition
8	deposed prior to you previously, so it	8	testimony in the AMS cases?
9	didn't matter.	9	A. One of the AMS cases and the Boston
10	THE WITNESS: That would be the most	10	Scientific case.
11	accurate version of what's available.	11	Q. So have you given a total of two
12	MR. THOMAS: Let's go off the record	12	depositions?
13	a second.	13	A. Yes.
14	(Discussion off the record)	14	Q. What is the product at issue in the
15	(Ms. Lewis joined the deposition by	15	AMS case where you've given a deposition?
16	teleconference.)	16	A. I believe it was the SUI.
17	MS. LEWIS: This is Christina Lewis.	17	Q. And what is the product at issue in
18	I'm with the Mueller Law Office, and we	18	the Boston Scientific case where you've given a
19	represent Mr. and Mrs. Edwards in this	19	deposition?
20	case.	20	A. There were several products. I can't
21	And I would like an agreement from	21	remember the names right now. Pinnacle maybe.
22	defense counsel that all objections by	22	There were five of them, but I can't remember
23	counsel for Huskey are the same as us. If	23	all the names.
24	we can have that agreement, I'll put my	24	Q. For what application were those
		1	
	Page 15		Page 17
1	Page 15 phone on mute so that I don't disrupt the	1	Page 17 products used? For the same application?
1 2		1 2	
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2	phone on mute so that I don't disrupt the deposition too much.	2	products used? For the same application?  A. Same application.
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	Page 18		Page 20
1	Q. Okay.	1	Dr. Dunn contacted you about preparing this
2	A. I believe.	2	expert report for use in this litigation, that
3	Q. Were you contacted directly about	3	you then began to your understanding of the
4	providing expert opinions with respect to	4	Ethicon mesh products used to treat stress
5	Ethicon, or did they go through Dr. Dunn?	5	urinary incontinence?
6	A. It came through Dr. Dunn.	6	A. A detailed understanding I had
7	Q. And were you on a conference call	7	been studying the effects of in vivo
8	with Dr. Dunn and counsel for plaintiffs in the	8	polypropylene oxidation for some time, maybe
9	case? Is that how you first got brought into	9	six months prior to that. But the details of
10	the case?	10	the Ethicon mesh started at the time I talked
11	A. No. Dr. Dunn called me in the	11	to Dr. Dunn.
12	evening and we discussed it.	12	Q. And the work that you did on the
13	Q. And what did Dr. Dunn tell you?	13	the six months work that you just discussed
14	A. That the attorneys at Wexler Wallace	14	that you did was with respect to the meshes of
15	wanted us to write an expert report for the	15	other manufacturers?
16	Ethicon case.	16	A. With respect to the meshes of other
17	Q. And did you and Dr. Dunn discuss the	17	manufacturers and also the oxidative
18	details of the scope of the expert report that	18	degradation of polypropylene in general.
19	you were preparing for the Ethicon case?	19	Q. Was the work that you did with
20	A. Yes.	20	respect to the Ethicon SUI mesh products
21	Q. And tell me what you discussed during	21	different from the work that you did analyzing
22	that call about the scope of the report.	22	the AMS products or the Boston Scientific
23	A. Well, the scope of the report would	23	products?
24	primarily be teaching with respect to the	24	A. It was different in the sense that we
	Page 19		Dago 21
	<u> </u>		Page 21
1	oxidation of polypropylene. We didn't have any	1	didn't have samples, either materials as made
1 2		1 2	
	oxidation of polypropylene. We didn't have any	l .	didn't have samples, either materials as made
2	oxidation of polypropylene. We didn't have any samples. So it was all the report was	2	didn't have samples, either materials as made or materials that had been explanted from the
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	Page 22		Page 24
1	Dr. Dunn had some materials from manufacturers	1	a different case. So I guess I'm concerned
2	and I don't remember exactly what. But	2	about disclosing something I'm not allowed to
3	personally I have not requested samples.	3	disclose.
4	Q. Did you have conversations with	4	Q. Would you like to consult with
5	Dr. Dunn about the availability of mesh samples	5	counsel?
6	for testing?	6	A. I would, if that would be okay.
7	A. I think in this case, to the extent	7	Q. Just for the record, just for your
8	that we didn't have them.	8	benefit, I'm going to want to know all the
9	Q. My question was, did you have	9	kinds of tests that were conducted on the AMS
10	conversations with Dr. Dunn about the	10	and Boston Scientific meshes and the purposes
11	availability of mesh samples for testing?	11	of those tests.
12	A. I mean, we discussed it. But the	12	If he's not going to be permitted to
13	problem was we didn't have the samples. So	13	answer that, then we'll figure out the next
14	they weren't available.	14	path to take.
15	Q. Did you request samples to conduct	15	MR. JACKSON: The question is
16	testing?	16	how far the protective orders go in the
17	A. I did not. I don't know what he did.	17	state courts that are involved. So Boston
18	But I know that the time was short between when	18	Scientific state court litigation was in
19	we had to get the report submitted and when the	19	Delaware and Massachusetts. And the AMS
20	request came. So there was also a time	20	litigation was at the MDL level.
21	constraint. There wasn't time to do it.	21	MR. THOMAS: Just so you know, I'm
22	Q. Now, did the work that you did in the	22	not going to argue with you about it.
23	AMS and Boston Scientific litigation follow the	23	Either you're going to let him answer or
24	same pattern in terms of what you did for those	24	you're not. I am going to go to court and
	Page 23		Page 25
			1490 23
1	cases?	1	seek to get the answers because I think
1 2	cases? A. Well, in the AMS and Boston	1 2	
	A. Well, in the AMS and Boston Scientific studies, we had exemplars and we had		seek to get the answers because I think
2	A. Well, in the AMS and Boston Scientific studies, we had exemplars and we had in some cases explanted materials. There may	2	seek to get the answers because I think it's very important to what's going on here.  So either he's going to answer or
2	A. Well, in the AMS and Boston Scientific studies, we had exemplars and we had in some cases explanted materials. There may have been materials from Ethicon. I just don't	2 3	seek to get the answers because I think it's very important to what's going on here.
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2 3 4 5	A. Well, in the AMS and Boston Scientific studies, we had exemplars and we had in some cases explanted materials. There may have been materials from Ethicon. I just don't remember because it wasn't part of that specific case. And Dr. Dunn did that testing,	2 3 4 5 6 7	seek to get the answers because I think it's very important to what's going on here.  So either he's going to answer or he's not. I'm not going to argue with you about it.  MR. JACKSON: I think the questions
2 3 4 5 6	A. Well, in the AMS and Boston Scientific studies, we had exemplars and we had in some cases explanted materials. There may have been materials from Ethicon. I just don't remember because it wasn't part of that specific case. And Dr. Dunn did that testing, and he would know.	2 3 4 5 6	seek to get the answers because I think it's very important to what's going on here.  So either he's going to answer or he's not. I'm not going to argue with you about it.
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	Page 26		Page 28
1	well, I don't know about the SCN. I can't	1	Q. In addition to the tests conducted on
2	remember.	2	the exemplar meshes, were the same tests
3	We also did x-ray photoelectron	3	conducted on explanted meshes?
4	spectroscopy or XPS. That's a surface method	4	A. Only for one of the AMS cases. We
5	where we can detect products of oxidative	5	had some explanted mesh and we did XPS on that
6	degradation on the surface.	6	mesh.
7	We also did FTIR. Again, Dr. Dunn	7	Q. For what purpose did you conduct XPS
8	did all of these studies I know for the AMS, I	8	testing on the AMS explanted mesh?
9	believe for the Boston Scientific as well.	9	A. To identify the presence of carbonyl
10	Ethicon, I can't remember. It's not in my	10	and hydroxyle groups similar to the exemplars.
11	report so I don't and Dr. Dunn did it. So I	11	Q. When you tested the explanted mesh
12	don't remember what we did there.	12	from AMS, was it necessary to prepare that mesh
13	Q. The purpose of the GPC testing is to	13	explant for testing?
14	do what?	14	A. The preparation of the explant was
15	A. Measure the molecular weight.	15	done by Dr. Iakovlev, who is at the University
16	Q. What does molecular weight tell you	16	of Toronto.
17	in the context of oxidation?	17	Q. Did you or Dr. Dunn have any
18	A. Well, if the oxidation is	18	involvement in consulting with Dr. Iakovlev
19	sufficiently severe. So oxidation comes from	19	about the preparation of the explant for XPS
20	the surface inward. If the oxidative	20	testing?
21	degradation is severe enough, say during	21	A. We did.
22	processing or after implantation, you could see	22	Q. And tell me about your conversations
23	a reduction in molecular weight which can	23	with Dr. Iakovlev about the appropriate way to
24	correlate with reduction in ductility and	24	prepare this sample for analysis.
	Page 27		Page 29
1	Page 27 embrittlement. So that was the GPC	1	A. Well, we had it shipped to us wet.
1 2	embrittlement. So that was the GPC measurement.	1 2	A. Well, we had it shipped to us wet.  Dr. Iakovlev
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Page 30 Page 32 1 Q. What concerns did you have about any 1 Dr. Dunn has been handling those types of 2 impact Formalin may have on the sample that you 2 3 3 were going to test? Q. Going back to the AMS explant you and 4 A. We didn't have any concerns because 4 Dr. Dunn analyzed, you said you conducted XPS 5 polypropylene and Formalin are compatible. 5 testing. Any other testing you conducted on 6 Q. At the time that you analyzed the 6 that AMS explant? 7 mesh explant from AMS that you had shipped in 7 A. No. I mean, the amount of sample is 8 saline, did you analyze the extent to which 8 very small. Dr. Dunn may have done -- he may 9 9 Formalin would interact with proteins on the have done FTIR. I can't remember. But I think 10 surface of the mesh explant? 10 the samples are very small. That's one 11 A. No. Dr. Iakovlev desiccated the 11 advantage of XPS, is that we can probe a very 12 explants manually, from what I remember. He 12 small surface. removed extra tissue that he could find and 13 13 So to my knowledge, what I can 14 then shipped them to us dry for the XPS 14 remember is we only did XPS on those. 15 testing. 15 Q. What was the goal of conducting the 16 Q. I'm sorry. I misunderstood your 16 testing on the AMS explanted mesh? 17 answer. I thought you told me a minute ago 17 A. It was to look for presence of 18 that you received the mesh explant wet. 18 hydroxyle and carbonyl groups on the surface 19 A. Dr. Iakovlev did. He received the 19 that are associated with polypropylene 20 mesh explant from the hospital. He prepared 20 degradation. 21 the sample for XPS and then shipped it to us 21 Q. And what do the hydroxyle and 22 dry after he had removed the tissue from the 22 carbonyl groups tell you if you find them on 23 23 these explanted meshes? sample. 24 Q. I see. Did -- how did Dr. Iakovlev 24 MR. JACKSON: Object to the form. Page 31 Page 33 1 clean the sample? 1 A. Well, you can do a similar approach 2 A. I can't remember the details. It was 2 using FTIR that's in the literature where it 3 3 a different case, so I didn't review this. So tells you that -- polypropylene is a 4 4 hydrocarbon. So there shouldn't be any how much detail again should I --5 MR. JACKSON: If you can, answer the 5 carbonyl and hydroxyle groups. So if you see 6 6 these species, it's an indication of oxidation question. 7 A. In this case, I really can't remember 7 of the surface. 8 exactly how he -- he did it. I know that he 8 This has been done by FTIR, also, in 9 had some mesh samples that he had scraped and 9 the past. But XPS, we believe, is more 10 some that he had manually dissected just to 10 sensitive. 11 remove the tissue. But it was all done in O. More sensitive than what? 11 12 things like saline or dry. 12 A. FTIR. 13 To my knowledge, I can't remember any 13 Q. In what respect is XPS more sensitive 14 processing of Formalin. But I'm going on my 14 than FTIR? 15 memory, and it was a different case. 15 A. XPS gives atomic percents, so percent 16 Q. All right. Was there any effort to 16 carbon, percent oxygen, percent nitrogen. And 17 test explanted meshes from the Boston 17 it also provides details about the state of the 18 Scientific litigation? 18 bonding. So it can tell you whether there's 19 A. I'm not sure what you mean by "any 19 bound oxygen on the surface. 20 effort." We didn't have the explant, so we 20 Q. Why wasn't GPC testing conducted on couldn't do it. 21 21 the AMS mesh explant? 22 Q. Did you request explants from Boston 22 A. There wasn't enough material, and GPC 23 Scientific to conduct tests? 23 takes quite a bit more material. 24 A. I believe we did. But then again, 24 Q. In the hierarchy of tests, it

Page 34 Page 36 1 provides you helpful information to understand 1 happening at earlier time points before you 2 the extent to which degradation may have 2 have a lot of molecular weight loss, and then 3 occurred, where does GPC fit? 3 GPC would actually measure that loss in 4 MR. JACKSON: Object to the form. 4 molecular weight. So it's measuring something 5 A. Well, I believe the GPC would be 5 different. 6 below XPS in priority because GPC is a bulk 6 Q. Do you agree with this statement: A 7 7 measurement. XPS is a surface measurement. molecular weight analysis is really going to be 8 Oxidative degradation proceeds from the surface 8 more accurate, I think, than to try to look for 9 inward. So XPS is going to provide more 9 degradation than with the FTIR for these 10 10 detailed information. explanted meshes? 11 Q. (By Mr. Thomas) How does GPC compare 11 A. It depends on the context of the 12 to FTIR? 12 statement. I mean -- like I said, GPC is going 13 13 to tell you whether there's a loss of molecular A. FTIR is also a method primarily for 14 looking at the oxidized species on the surface. 14 weight in the material. FTIR -- the problem 15 with FTIR is it could be looking at -- you 15 GPC is measuring the bulk molecular weight of 16 can't interpret it as directly as XPS in terms 16 the polymer. Q. Which is more sensitive, FTIR or GPC? 17 17 of the source of the carbonyl or the hydroxyle 18 groups. And it has to be fairly far along in 18 A. I don't know if I could answer that. 19 They measure different things. GPC measures 19 the degradation before you can see it. 20 20 Q. What has to be fairly far along in molecular weight and FTIR is measuring chemical 21 the degradation before you can see it? I 21 composition. 22 didn't understand your answer. I'm sorry. 2.2 Q. Is it fair to understand that a 23 A. Well, I'm saying that FTIR, I think 23 molecular weight analysis is going to be more 24 is -- XPS, you can see what's happening, I 24 accurate than an FTIR analysis to understand Page 35 Page 37 1 the extent to which polypropylene is degraded? 1 believe, at earlier time points than you could 2 A. I wouldn't agree with that -- the 2 with FTIR because the peaks aren't always as 3 only way you could support that statement is if 3 resolved as well. XPS is, I think more precise. 4 you could measure GPC of that actual degraded 4 Q. So is it your position that XPS is 5 5 layer. But, again, that's going to be the best test method to understand the extent 6 6 difficult. to which oxidation occurs on the surface of 7 GPC is essentially a volume average 7 explanted meshes? 8 over the entire fiber. So it doesn't really 8 A. I would say that XPS can -- I think 9 tell you what's going on on the surface because 9 the advantage of XPS is it can predict what's 10 it's averaged over the entire volume. 10 happening at very early time points before 11 Q. Have you ever testified that 11 there's molecular weight loss. 12 molecular weight analysis is more sensitive to 12 Molecular weight loss happens later 13 look at degradation than FTIR? 13 in the process. Those carbonyl and hydroxyle 14 14 A. They measure different things. So groups will form on the surface earlier. So 15 GPC measures molecular weight. FTIR measures 15 GPC is very effective for measuring molecular 16 the surface composition. And FTIR is, I don't 16 weight loss. I think what I'm saying here is 17 think is, as sensitive as XPS, but they just 17 that XPS can predict those events at very early 18 measure different things. 18 time points before there's molecular weight 19 I think GPC is an important 19 loss. That's what I'm saying. 20 measure -- if you see degradation by GPC, that 20 Q. What kind of equipment is necessary 21 means it's even -- it's fairly degraded, if 21 to conduct XPS testing? 22 you're seeing loss in molecular weight. 22 A. Well, there's a specific instrument 23 But I wouldn't use the word 23 in XPS that's a high vacuum device. So you 24 sensitive. I would say XPS can tell you what's 24 have to -- it's a fairly expensive instrument.

Page 40 Page 38 1 Q. And how is that test conducted? 1 search? 2 MR. JACKSON: Object to the form. 2 A. So I've conducted my own literature 3 A. Dr. Bridget Rogers at Vanderbilt did 3 search on -- I have done my own searches for 4 4 the XPS testing. That's her area of expertise. oxidative degradation of polypropylene. 5 The actual details of how the test is 5 For the internal documents, we were performed, she would be -- she's the one that 6 6 provided with documents by the attorneys. We 7 7 did the testing for this. I basically talked didn't have access to those through literature. 8 with her about interpretation of the data. 8 Q. Is it fair to understand, though, 9 9 Q. (By Mr. Thomas) Okay. How is XPS specifically for the Ethicon mesh, that you 10 10 testing different from EDX testing? didn't conduct an internal -- strike that. A. Well, EDX, in my understanding, is 11 11 Is it fair to understand with respect 12 more like SCM where you would look for specific 12 to the Ethicon mesh that you didn't conduct a 13 atoms in the background. But my understanding 13 new literature search about the oxidative 14 is that XPS is more sensitive than EDX. That's 14 effects on polypropylene? 15 A. Not for specific Ethicon products. I 15 why we did XPS. 16 was focusing more on the mechanisms of 16 Q. Did you conduct any EDX testing on oxidative polypropylene in general. 17 any of the meshes you analyzed? 17 18 Q. As a part of your work and your 18 A. Not to my knowledge, but Dr. Dunn 19 would be able to speak to that. 19 opinions in this case, did you ever focus on 20 20 the mechanisms of oxidation of polypropylene Q. The reason why you and Dr. Dunn 21 for Ethicon products specifically? 21 conducted the tests that you did on the AMS and 22 22 Boston Scientific meshes was to understand the A. Could you repeat that? 23 Q. Doctor, you testified -- strike that. 23 extent to which these meshes may undergo 24 Doctor, in the course of your work in this 24 oxidative degradation? Page 39 Page 41 1 A. Yes. We were looking for evidence of case, did you ever analyze the extent to which 1 2 oxidative degradation. The advantage of XPS is 2 Ethicon mesh specifically degrades? 3 3 A. There was some internal documents that you can see what's happening at early time 4 points, and it doesn't require a lot of 4 that there were references in one of these is 5 5 sampling. And you can probe the surface with addressed in the rebuttal report. We just 6 it. That's really the advantages of it. 6 received a document. 7 Q. Okay. Dr. Guelcher, go back to a 7 There was a 1987 study. There was a 8 8 month ago or so when you were first contacted human study and a study in dogs that were done 9 by Dr. Dunn about your work in this case, and 9 by Ethicon that discussed oxidative degradation 10 you had this conversation with Dr. Dunn you 10 of polypropylene. These were with Prolene 11 just told me about, and you decided what work 11 sutures, I believe, and not the mesh. It was 12 you were going to do and you didn't have any 12 the sutures. 13 exemplars and you didn't have any explanted 13 Q. Other than the internal documents 14 meshes. What did you do to acquaint yourself 14 that you described, did you conduct any 15 with the Ethicon product? 15 investigation to determine the mechanism of any 16 MR. JACKSON: Object to the form. 16 oxidative degradation that Prolene mesh 17 17 A. We reviewed papers on it, internal undergoes? 18 documents, published papers describing the 18 A. Not specific to Prolene. I think in 19 product. 19 some of the literature studies, Prolene or TVT 20 Q. (By Mr. Thomas) Are all the 20 Ethicon meshes were reviewed. But it's 21 documents that you reviewed to familiarize 21 polypropylene, so we were focusing really on 22 yourself with the product in Exhibits 2 and 3? 22 the oxidation of the polypropylene molecule. 23 A. Yes. 23 Q. What did you do in formation of your 24 Q. Did you conduct your own literature 24 opinions in this case to understand the history

of Prolene?  A. I reviewed the documents that are in the reference materials.  Q. Do you know how long Prolenc has been in the marker?  A. I believe since the 1960s.  O. Do you know the application for Prolene since the 1960s?  A. I know it's used in sutures and hermia mesh and in the pelvic floor meshes.  I. Q. Do you know how Prolenc happened to be introduced as a medical device in the 1960s?  A. That's a regulatory term, I presume.  O. What's your understanding of what a new drug application, NDA?  A. That's a regulatory term, I presume.  O. What's your understanding of what a new drug application, NDA?  A. That's a regulatory term, I presume.  O. What's your understanding of what a new drug application. My work is more in devices where we're dealing with PMAs and 25 familiar with.  A. I don't know that I'm familiar with the work may application. My work is more in devices where we're dealing with PMAs and 25 familiar with.  A. I would presume that when a company develops a new drug, they submit a new drug application. But that specific term, I don't know the details of it.  Q. In learning about the polypropylene used in Prolene, did you review any of the testing conducted by Ethicon since the 1960s in connection with the safety and efficacy of the polypropylene used in Prolene,  A. That's this one.  A. That's this one.  A. That's this one.  Q. What's your understanding of what a lift in the Nickson study for the proper of the polypropylene used in Prolene,  A. That's this one.  A. That's this one.  Q. I iddn't see that referenced in your report. For what purpose did you look at the 17-year data that's contained in that study is the same mesh that in the work of the polypropylene used in Prolene,  A. I would presume that when a company develops a new drug, they submit a new drug application. But that specific leven, I don't submit the prolene?  A. Primarily, the dog study and luman study were the primary documents that I reviewed.  A. The seven-year dog study would be the seven-year dog study?  A. The seven-		Page 42		Page 44
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4 you've looked at to understand specifically the testing done by Ethicon on the safety and fifties or the safety and fire since the 1960s?  8 Prolene since the 1960s?  9 A. I know it's used in sutures and lebrain mesh and in the pelvic floor meshes.  10 Do you know how Prolenc happened to be introduced as a medical device in the 1960s?  11 A. I don't remember the history of that.  12 A. I don't remember the history of that.  13 A. I don't remember the history of that.  14 Q. Are you familiar with a term known as a new drug application, NDA?  15 A. That's a regulatory term, I presume.  17 Q. What's your understanding of what a new drug application. My work is more in devices where we're dealing with PMAs and 22 510Ks. And a new drug application Irn not as 33 familiar with.  10 Q. What's your general understanding of what a new drug application is?  11 what that is, to the extent that you have one?  22 A. I would presume that when a company develops a new drug, they submit a new drug application. But that specific term, I don't know the details of it.  23 Q. In learning about the polypropylene used in Prolene, did you review any of the testing conducted by Ethicon since the 1960s in compection with the safety and efficacy of the polypropylene used in Prolene, did you review any of the testing conducted by Ethicon since the 1960s in compection with the safety and efficacy of the polypropylene. But whether or not you can study that you have in front of you, the 17-year data?  11 A. Primarily, the dog study and human study were the primary documents that I reviewed.  12 Q. And the dog study would be the seven-year dog study?  13 Q. What was the human study, It was sutures seplanted from vascular grafts in luman patients. That one was done in 1987.  24 Q. That must be in your rebutal report?  25 Int must be safety and entire the esting done by Ethicon on the safety and estinately and prol	2	A. I reviewed the documents that are in	2	problem.
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6 A. I believe since the 1960s. 7 Q. Do you know the application for 8 Prolene since the 1960s? 9 A. I know it's used in sutures and 10 herriia mesh and in the pelvic floor meshes. 11 Q. Do you know how Prolenc happened to be introduced as a medical device in the 1960s? 13 A. I don't remember the history of that. 14 Q. Are you familiar with a term known as a new drug application, NDA? 15 A. That's a regulatory term, I presume. 17 Q. What's your understanding of what a new drug application is? 19 A. I don't know that T'm familiar with the new drug application. My work is more in devices where we're dealing with PMAs and 22 510ks. And a new drug application I'm not as 23 familiar with. 24 Q. What's your general understanding of 24 develops a new drug, they submit a new drug application. But that specific term, I don't know the details of it. 25 Q. In learning about the polypropylene used in Prolenc since the polypropylene used in Prolenc in the 60s? 26 A. I would presume that twhen a company develops a new drug, they submit a new drug application. But that specific term, I don't know the details of it. 26 Q. In learning about the polypropylene used in Prolenc in the 1960s in connection with the safety and efficacy of the polypropylene used in Prolenc? 27 A. Primarily, the dog study and human study were the primary documents that I reviewed. 28 Q. And the dog study would be the seven-year dog study? 29 A. I wouldn't call it a human study. It was sutures explanted from vascular grafts in thuman patients. That none was done in 1987. 29 A. I wouldn't call it a human study. It was sutures explanted from vascular grafts in human patients. That one was done in 1987. 20 Q. That must be in your rebuttal report? 21 do Polypu know the time in proving the polypropylene used in Prolenc? 22 do Polypu anderstanding between TVT and TVT-O in the approach and the instruments. 23 familiar with. 24 Q. Mat was the human study you referred to? 25 Q. And the dog study would be the seven-year dog study published in 1992. 26 A. I wouldn'	4	Q. Do you know how long Prolene has been	4	you've looked at to understand specifically the
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A. It is. 24 says in the back here that he's a consultant	22	O. That must be in your rebuttal report?	23	I mean, Dr. Nielson is I think it

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for Ethicon. So, you know, he has interest in success of the material. It's one study done by a clinician who is pretty connected to the material.

Q. Do the findings in the Nielson study, the 17-year data support your opinions in this case?

MR. JACKSON: Object to the form.

- A. There was an erosion in one of the meshes that would be consistent with my opinion that polypropylene undergoes surface oxidation which leads to embrittlement, can lead to erosion and other types of complications.
- Q. There's nothing in that study to suggest that there's degradation involved in the one erosion that's there, is there?
  - A. I don't think they looked at that.
- Q. Is that the only point in the Nielson study upon which you rely to support your opinions, the fact that an erosion occurred?
- A. There wasn't a lot of -- I mean, the examinations that these women received, some of them they talked to over the phone. It was a quality-of-life survey in older women. So to

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- mesh or suture in connection with your opinions in the case?
- A. I believe so. Well, yeah, for
   specific -- yes, I believe so, for specific
   Ethicon products that I can remember.
  - Q. Right. Dr. Guelcher, have you ever used the term "gold standard"?
  - A. I think a lot of people use this term. It can apply to a lot of -- it depends on the context of what you mean.
  - Q. How do you use the term "gold standard" in your work?

A. I don't think I use it very much. It can be used in the context of almost like a clinical control. So in my work in bone grafting, a lot of people refer to autograft bone as the gold standard. It's the most successful approach for healing bone.

That doesn't necessarily mean it's preferred or the best way to do it. It's just what's known to be the most effective. So autograft bone has its deficiencies. People still refer to it as the gold standard because it's the best known approach basically.

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me, it's a bit difficult to interpret. Were there other types of complications? It's hard to say.

The data just aren't that -- they say in here that a lot of the patients didn't want these invasive evaluations. So it's very qualitative. It's difficult for me to take much away from it. It's just another piece of information.

- Q. All I'm trying to understand is you've obviously pointed this out to me as something in your file that's of significance to you, and I need to know the significance of it to your opinions in the case.
- A. So, I mean, I thought I answered it. There was one patient had an erosion. And it's difficult for me to rely heavily on this document just because of the types of data that was collected. It wasn't specific to the types of questions that we're asking. I would say it was more inconclusive, if that's what you're asking.
- Q. Okay. So have we identified now the studies that you looked at specific to Ethicon

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- Q. And in the bone graft context, there's no perfect bone graft procedure; fair?
- A. Well, the problem with autograft is that you have to get it from somewhere. That introduces a lot of limitations. And so there's a number of different approaches that can be used.
  - Q. At least that is -- the autograft bone procedure is known as the gold standard in your area of expertise because it's the best that you-all have available at this time; is that fair?
  - A. That's the way a lot of -- I think that's -- I mean, understanding within the field is that autograft is the gold standard in terms of healing.
  - Q. Have you made any investigation to determine the extent to which the use of polypropylene in tissue repair has been considered the gold standard since the '60s?
  - A. Well, I don't know that I would agree with that statement. I think some of Ethicon's own documents and e-mails say that they're moving toward these PVDF meshes because the

Page 50 Page 52 1 inflammatory response is less severe. 1 Q. Are you referring to Ethicon 2 Q. My question is very simple: Have you 2 documents now? 3 3 made any investigation to determine the extent A. Yes. 4 to which polypropylene has been considered the 4 Q. Are you looking at the seven-year dog 5 gold standard in tissue repair since the 1960s? 5 study? 6 A. Well, I think I just said other 6 A. I am. So they were looking at 7 7 people may consider it the gold standard. I alternatives. One of the alternatives was 8 looked into these documents, and I don't 8 Ethylon, Novafil, Prolene, and they point out 9 consider it the gold standard. It's an 9 that -- let me look at this for a minute. 10 unstable material in my opinion. 10 So in this dog study, some of the 11 It may have been the best one 11 dogs were implanted with PTVF sutures in 1987, 12 available in 1960, but I think recent evidence 12 and I believe that -- so this report is 13 points to the contrary that there are 13 basically saying PVF and Novafil did not show 14 alternative materials available. 14 the surface cracks and surface oxidation that 15 I think even Ethicon's own e-mails 15 Prolene was showing. So this would be 1992, I 16 there are statements that we need to move to a 16 think this was published. Yeah. 17 different material because of problems with 17 Q. Is it your understanding that the 18 polypropylene. 18 Ethicon dog study was published? 19 Q. And what material -- do you have an 19 A. I mean published internally. It 20 opinion that there's a better material than looks like it's an internal report to me. 20 21 polypropylene in the treatment of stress That's what I meant by published. Submitted, I 21 22 urinary incontinence? 22 should say. 23 A. That opinion really wasn't the 23 Q. Doctor. Is there any significance to 24 subject of my report. I can say that in the 24 your opinions in this case, whether you are Page 51 Page 53 1 1 looking at Prolene that's sutured or Prolene in documents that I reviewed, there were Ethicon 2 employees and I believe even consultants 2 mesh, in terms of the oxidative degradation 3 pointing out that PVDF, for example -- there 3 issues? 4 are some papers that have pointed out that PVDF 4 A. Well, there's a number of comments in 5 would be a better choice, but I didn't look at 5 the internal Ethicon documents about moving 6 that specifically in my report. 6 from heavy-weight to light-weight mesh, the 7 Q. Do you know what PVDF is? 7 notion being just having less polypropylene has 8 A. Polyvinylidene fluoride. 8 been associated with a reduced inflammatory 9 Q. Have you ever studied the use of 9 response. 10 polyvinylidene fluoride in the context of 10 Mesh is different than sutures. It's 11 tissue repair? 11 implanted in a different anatomic site where 12 12 there could be differences in load-bearing. A. No. Like I said, that's outside the 13 context of my report. I'm just noting that 13 There could be differences in the cellular 14 14 even Ethicon employees are doubting this notion infiltrate. There's many types of differences. 15 that polypropylene is the only thing available. 15 So I don't know that -- you can learn 16 Q. Do you know of any PVDF mesh 16 some things from the suture studies, but it's 17 available for sale in the United States? 17 not necessarily representative of how much 18 A. No. It would require another 18 degradation you would see in a mesh. I would 19 regulatory filing. 19 think you would see more in a mesh. 20 Q. Now, at what point, to your 20 Q. Why? knowledge, was PVDF available as an 21 21 A. Because there's more polypropylene 22 alternative? 22 there. It's -- especially in the pelvic floor, A. I believe -- let me look at the 23 23 it's bearing a load, so it's under a different 24 document. 24 types of stresses and strains. So the

	Page 54		Page 56
1	consequences of those, oxidative degradation	1	Is there any material that can be used for
2	could be different in a mesh than you would see	2	medical implants that can be considered inert?
3	in a suture.	3	A. Some are less active than others. I
4	Q. Are your opinions in this case	4	don't know if it's anything that's completely
5	specific to meshes?	5	inert.
6	A. Well, I think my opinions relate to	6	Q. You continue and say, It's often
7	oxidative degradation of polypropylene and then	7	stabilized against the threat of oxidation by
8	how that can affect the mesh. That's my	8	adding antioxidants to the molten polymer.
9	Q. I understand that. But are your	9	These antioxidants are supposed to act as
10	opinions in this case specific to meshes and	10	scavengers that will react with any oxidative
11	not sutures?	11	species.
12	A. Yes. I'm not here to testify about	12	Do you know how, if at all, Ethicon
13	polypropylene sutures. I was looking at the	13	stabilized Prolene against the threat of
14	suture studies because it was the data that was	14	oxidation by adding antioxidants?
15	available to evaluate the body's response to	15	A. So there's some information in the
16	polypropylene.	16	internal documents I know they made some
17	Q. And are your opinions in this case	17	changes to stabilizer levels. The stabilizer
18	specific to the polypropylene mesh used for the	18	levels that I saw were reported as ranges.
19	treatment of stress urinary incontinence?	19	In the 1987 human explants, it was
20	MR. JACKSON: I'm going to object to	20	noted that the antioxidant was depleted in the
21	form.	21	surface oxidized layer on the polypropylene.
22	A. So, again, my opinions are generally	22	My understanding was the oxidants
23	to oxidative degradation of polypropylene and	23	were added to protect against oxidation during
24	how that can affect its performance in the SUI	24	thermal processing. But to dose an antioxidant
	•		
	Page 55		Page 57
1	Page 55 application.	1	Page 57 over the lifetime of the device in vivo would
1 2		1 2	
	application.  Q. (By Mr. Thomas) You've not looked at the extent to which oxidative degradation of		over the lifetime of the device in vivo would be I don't know if that can be done. That's what I'm saying in this paragraph.
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2 3 4	application.  Q. (By Mr. Thomas) You've not looked at the extent to which oxidative degradation of polypropylene can impact the performance of Prolene in other applications?  A. Like hernia or something?	2 3 4	over the lifetime of the device in vivo would be I don't know if that can be done. That's what I'm saying in this paragraph. Q. What did Ethicon do to stabilize its
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	Page 58		Page 60
1	A. Yes.	1	documents I guess there are 20 documents
2	Q. When did you first see those	2	in a notebook which we've marked earlier as
3	documents?	3	Exhibit No. 3.
4	A. Yesterday, I believe.	4	(Exhibit 5 was marked.)
5	Q. And how did you obtain those	5	Q. (By Mr. Thomas) Those 20 documents
6	documents?	6	are the documents upon which you rely for the
7	A. Dr. Dunn asked for this document, I	7	substance of your rebuttal report, Exhibit 5?
8	believe. I got it from him. I believe he	8	MR. JACKSON: Object to the form.
9	asked the attorneys for it.	9	A. Well, the rebuttal report also
10	O. And what does	10	includes the documents submitted. The rebuttal
11	A. You asked about the antioxidants.	11	report also includes documents in the first
12	Q. Correct.	12	report.
13	A. I believe that this report I need	13	Q. Okay. But the new documents for the
14	to find it. Dilauryl thiodipropionate, DLTDP,	14	rebuttal report are contained in the notebook,
15	is what I believed I believe they were using	15	Exhibit 3, that you brought here with you this
16	this as antioxidant in the suture at this time.	16	morning?
17	It appears reduced in the two-year sample	17	MR. JACKSON: Object to the form.
18	spectra and further reduced in the eight-year	18	A. I believe that they are.
19	sample spectra. And in the material they	19	Q. (By Mr. Thomas) Other than document
20	scraped off the surface, they did not find any	20	No. 18 in Exhibit No. 3, do you have any other
21	of it. That's what the report says.	21	documents to support your opinion that the
22	Q. Okay. Just for the record, that's	22	antioxidants used in the Prolene mesh were not
23	marked as document No. 18?	23	sufficient to stabilize against the threat of
24	A. Yes.	24	oxidation?
	Page 59		Page 61
1	Page 59  Q. In Exhibit No. 3; is that right?	1	Page 61  A. This is the only document that has
1 2	<ul><li>Q. In Exhibit No. 3; is that right?</li><li>A. Yes, that's right.</li></ul>	1 2	A. This is the only document that has the in vivo analysis of that.
	Q. In Exhibit No. 3; is that right?		A. This is the only document that has
2	<ul><li>Q. In Exhibit No. 3; is that right?</li><li>A. Yes, that's right.</li><li>Q. And you received that document yesterday. Any other documents that you</li></ul>	2	A. This is the only document that has the in vivo analysis of that.
2 3	<ul><li>Q. In Exhibit No. 3; is that right?</li><li>A. Yes, that's right.</li><li>Q. And you received that document yesterday. Any other documents that you received yesterday that you rely on for your</li></ul>	2 3	A. This is the only document that has the in vivo analysis of that.  Q. Okay. Going back to my original question, what did you do to understand how Ethicon used antioxidants to stabilize Prolene
2 3 4	<ul><li>Q. In Exhibit No. 3; is that right?</li><li>A. Yes, that's right.</li><li>Q. And you received that document yesterday. Any other documents that you received yesterday that you rely on for your opinions in the case?</li></ul>	2 3 4	<ul><li>A. This is the only document that has the in vivo analysis of that.</li><li>Q. Okay. Going back to my original question, what did you do to understand how</li></ul>
2 3 4 5	<ul> <li>Q. In Exhibit No. 3; is that right?</li> <li>A. Yes, that's right.</li> <li>Q. And you received that document yesterday. Any other documents that you received yesterday that you rely on for your opinions in the case?</li> <li>A. Well, they're in this notebook.</li> </ul>	2 3 4 5	A. This is the only document that has the in vivo analysis of that.  Q. Okay. Going back to my original question, what did you do to understand how Ethicon used antioxidants to stabilize Prolene against the threat of oxidation?  A. So Dr. Dunn was looking at this more
2 3 4 5 6	<ul> <li>Q. In Exhibit No. 3; is that right?</li> <li>A. Yes, that's right.</li> <li>Q. And you received that document yesterday. Any other documents that you received yesterday that you rely on for your opinions in the case?</li> <li>A. Well, they're in this notebook.</li> <li>Q. This is the new binder?</li> </ul>	2 3 4 5 6 7 8	A. This is the only document that has the in vivo analysis of that.  Q. Okay. Going back to my original question, what did you do to understand how Ethicon used antioxidants to stabilize Prolene against the threat of oxidation?  A. So Dr. Dunn was looking at this more in his report. I discussed this topic with
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	<ul> <li>Q. In Exhibit No. 3; is that right?</li> <li>A. Yes, that's right.</li> <li>Q. And you received that document yesterday. Any other documents that you received yesterday that you rely on for your opinions in the case?</li> <li>A. Well, they're in this notebook.</li> <li>Q. This is the new binder?</li> <li>A. Yes. So this was one that I brought with me. These are some</li> <li>Q. I see.</li> <li>A. Most of this I got from Dr. Dunn. He had requested a number of these documents, and he got them from attorneys and we reviewed them yesterday.</li> <li>Q. I see. So the documents in Exhibit No. 3 go with the rebuttal report that you were served yesterday?</li> <li>A. They do, yeah.</li> <li>MR. THOMAS: For the record, I'm</li> </ul>	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	A. This is the only document that has the in vivo analysis of that.  Q. Okay. Going back to my original question, what did you do to understand how Ethicon used antioxidants to stabilize Prolene against the threat of oxidation?  A. So Dr. Dunn was looking at this more in his report. I discussed this topic with Dr. Dunn. He showed me some documents providing ranges of the antioxidant that were provided.  There were some changes made to the antioxidant levels as well. I'm not sure that we were able to identify what those were. But I do believe there were some documents stating that the antioxidant levels were changed, but Dr. Dunn was looking at that. I discussed it with him.  Q. Do you have an opinion that you're prepared to offer to a reasonable degree of
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q. In Exhibit No. 3; is that right? A. Yes, that's right. Q. And you received that document yesterday. Any other documents that you received yesterday that you rely on for your opinions in the case? A. Well, they're in this notebook. Q. This is the new binder? A. Yes. So this was one that I brought with me. These are some Q. I see. A. Most of this I got from Dr. Dunn. He had requested a number of these documents, and he got them from attorneys and we reviewed them yesterday. Q. I see. So the documents in Exhibit No. 3 go with the rebuttal report that you were served yesterday? A. They do, yeah. MR. THOMAS: For the record, I'm going to mark as Exhibit No. 5 Exhibit	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. This is the only document that has the in vivo analysis of that.  Q. Okay. Going back to my original question, what did you do to understand how Ethicon used antioxidants to stabilize Prolene against the threat of oxidation?  A. So Dr. Dunn was looking at this more in his report. I discussed this topic with Dr. Dunn. He showed me some documents providing ranges of the antioxidant that were provided.  There were some changes made to the antioxidant levels as well. I'm not sure that we were able to identify what those were. But I do believe there were some documents stating that the antioxidant levels were changed, but Dr. Dunn was looking at that. I discussed it with him.  Q. Do you have an opinion that you're prepared to offer to a reasonable degree of scientific certainty that the antioxidant
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. In Exhibit No. 3; is that right? A. Yes, that's right. Q. And you received that document yesterday. Any other documents that you received yesterday that you rely on for your opinions in the case? A. Well, they're in this notebook. Q. This is the new binder? A. Yes. So this was one that I brought with me. These are some Q. I see. A. Most of this I got from Dr. Dunn. He had requested a number of these documents, and he got them from attorneys and we reviewed them yesterday. Q. I see. So the documents in Exhibit No. 3 go with the rebuttal report that you were served yesterday? A. They do, yeah. MR. THOMAS: For the record, I'm going to mark as Exhibit No. 5 Exhibit No. 5 is an expert rebuttal report from	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. This is the only document that has the in vivo analysis of that.  Q. Okay. Going back to my original question, what did you do to understand how Ethicon used antioxidants to stabilize Prolene against the threat of oxidation?  A. So Dr. Dunn was looking at this more in his report. I discussed this topic with Dr. Dunn. He showed me some documents providing ranges of the antioxidant that were provided.  There were some changes made to the antioxidant levels as well. I'm not sure that we were able to identify what those were. But I do believe there were some documents stating that the antioxidant levels were changed, but Dr. Dunn was looking at that. I discussed it with him.  Q. Do you have an opinion that you're prepared to offer to a reasonable degree of scientific certainty that the antioxidant package used by Ethicon for Prolene is
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Q. In Exhibit No. 3; is that right? A. Yes, that's right. Q. And you received that document yesterday. Any other documents that you received yesterday that you rely on for your opinions in the case? A. Well, they're in this notebook. Q. This is the new binder? A. Yes. So this was one that I brought with me. These are some Q. I see. A. Most of this I got from Dr. Dunn. He had requested a number of these documents, and he got them from attorneys and we reviewed them yesterday. Q. I see. So the documents in Exhibit No. 3 go with the rebuttal report that you were served yesterday? A. They do, yeah. MR. THOMAS: For the record, I'm going to mark as Exhibit No. 5 Exhibit No. 5 is an expert rebuttal report from Scott Guelcher, Ph.D., that I received for	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	A. This is the only document that has the in vivo analysis of that.  Q. Okay. Going back to my original question, what did you do to understand how Ethicon used antioxidants to stabilize Prolene against the threat of oxidation?  A. So Dr. Dunn was looking at this more in his report. I discussed this topic with Dr. Dunn. He showed me some documents providing ranges of the antioxidant that were provided.  There were some changes made to the antioxidant levels as well. I'm not sure that we were able to identify what those were. But I do believe there were some documents stating that the antioxidant levels were changed, but Dr. Dunn was looking at that. I discussed it with him.  Q. Do you have an opinion that you're prepared to offer to a reasonable degree of scientific certainty that the antioxidant package used by Ethicon for Prolene is inadequate to protect against oxidation in
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. In Exhibit No. 3; is that right? A. Yes, that's right. Q. And you received that document yesterday. Any other documents that you received yesterday that you rely on for your opinions in the case? A. Well, they're in this notebook. Q. This is the new binder? A. Yes. So this was one that I brought with me. These are some Q. I see. A. Most of this I got from Dr. Dunn. He had requested a number of these documents, and he got them from attorneys and we reviewed them yesterday. Q. I see. So the documents in Exhibit No. 3 go with the rebuttal report that you were served yesterday? A. They do, yeah. MR. THOMAS: For the record, I'm going to mark as Exhibit No. 5 Exhibit No. 5 is an expert rebuttal report from	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. This is the only document that has the in vivo analysis of that.  Q. Okay. Going back to my original question, what did you do to understand how Ethicon used antioxidants to stabilize Prolene against the threat of oxidation?  A. So Dr. Dunn was looking at this more in his report. I discussed this topic with Dr. Dunn. He showed me some documents providing ranges of the antioxidant that were provided.  There were some changes made to the antioxidant levels as well. I'm not sure that we were able to identify what those were. But I do believe there were some documents stating that the antioxidant levels were changed, but Dr. Dunn was looking at that. I discussed it with him.  Q. Do you have an opinion that you're prepared to offer to a reasonable degree of scientific certainty that the antioxidant package used by Ethicon for Prolene is

Page 62 Page 64 1 A. My opinion is that the antioxidant 1 to be very difficult. No matter what 2 used cannot protect against oxidation in vivo. 2 antioxidant is added, it's going to be 3 3 gradually depleted over time. I believe that because of the teachings of Jim 4 Anderson that this chronic inflammatory 4 Q. What's the basis for your opinion 5 response foreign body reaction is ongoing and 5 that whatever antioxidant is available is going 6 will continue to oxidize material and deplete 6 to be depleted over time? 7 7 the antioxidant. A. Well, the paper by Jim Anderson and 8 That observation is basically 8 other papers that have shown that this foreign 9 9 supported by these studies on the sutures from body reaction is continuous and ongoing and 10 the human explants and, you know, consistent, I 10 it's going to continue as long as the material 11 think, with the field that you simply can't 11 is there. Eventually, that antioxidant is 12 protect a device over its lifetime. It's going 12 going to be depleted. 13 to be implanted in a patient over the patient's 13 I suppose you could put it in at very 14 lifetime with an antioxidant. Eventually, it 14 high doses, but then you're going to have 15 will be depleted. 15 toxicity concerns. To my knowledge, nobody has 16 Q. Can you tell me today what the 16 studied that, what's the amount of antioxidants antioxidant package that Ethicon used to 17 17 to add to protect it over its lifetime. protect the Prolene polypropylene from 18 18 Q. Is it your opinion that the 19 oxidation was? 19 antioxidant package Ethicon used is inadequate 20 A. I don't know what it is today. In 20 or that it can't be done? this report in 1987, it was DLTDP. 21 21 A. Well, my opinion is that the 22 Q. Is that all it was? 2.2 antioxidant used in 1987 is inadequate. That 23 A. That's what it says in this report. 23 opinion is supported by Ethicon's own data. 24 Q. Have you tried to determine the 24 I don't know what -- I don't remember Page 63 Page 65 1 specific antioxidant package Ethicon used to 1 what the antioxidant is that's being used 2 stabilize Prolene against the threat of 2 today, but my opinion would be that that would 3 3 oxidation? also be inadequate. Over time, it's just going A. Dr. Dunn and I looked at this. Like 4 to be depleted and you can't guarantee that 4 5 I said, our conclusion was that the documents 5 it's going to stay there. 6 Q. Okay. And the same would be true for 6 provided a range of antioxidant. It didn't 7 provide a specific dose. 7 any polypropylene used as a medical device; 8 Q. Can you tell me today as you sit here 8 fair? 9 in this chair the antioxidant package Ethicon 9 MR. JACKSON: Objection to form. 10 used to stabilize Prolene against the threat of 10 A. I don't believe polypropylene can be 11 11 stabilized effectively over its lifetime when oxidation? 12 12 A. I don't remember what it was. implanted in a human or animal. 13 Q. Is it your opinion, Doctor, that 13 Q. (By Mr. Thomas) What's the risk when there is no antioxidant package available that 14 you're unable to stabilize the polypropylene 14 15 can effectively stabilize polypropylene against 15 used as a medical implant over the life of the 16 the threat of oxidation? 16 implant? 17 A. I don't believe it's possible to 17 MR. JACKSON: Object to the form. 18 stabilize an implant against oxidation over its 18 A. Well, the risk is exactly what's 19 entire lifetime. I don't know that there's 19 pointed to in this Ethicon study. At two 20 much data on what the dosing should be. If 20 years, I don't believe they saw --21 it's dosed too high, that could cause problems. 21 Q. This is Tab 18 again, the Guidoin 22 There's papers that have noted that. 22 study? 23 The problem is it's an inherently 23 A. Yes. I need to review this again for 24 unstable material, and stabilizing it is going 24 just a minute. There are a lot of documents.

Page 66 Page 68 1 So I can say that as you go from two 1 antioxidant is. 2 to eight years, the amount of DLTP -- DLTDP was 2 Q. (By Mr. Thomas) Do you know whether 3 reduced, and in that surface oxidized layer it 3 there's more than one in 1987? 4 was gone. 4 A. In 1987, I don't know. This report 5 So I think this study supports the 5 just refers to DLTDP. That's -- it doesn't say 6 idea that stabilizing polypropylene against in 6 whether there's another one. It just talks 7 vivo degradation permanently for the lifetime 7 about DLTDP. Q. Have you made any effort to 8 of the patient is going to be very difficult. 8 9 9 Eventually, the material will oxidize and understand how Ethicon arrived at the 10 become embrittled. 10 antioxidants that it uses to stabilize Prolene 11 And those are the consequences, I 11 against the threat of oxidation? 12 believe, to not being stable. 12 MR. JACKSON: Object to the form. 13 Q. Okay. Are you aware of any study 13 A. Again, there were a limited number of 14 published in peer-reviewed literature which 14 references that we talked about. I believe 15 suggests that Ethicon Prolene loses its 15 reviewing some of those documents with 16 antioxidant package such that it oxidizes and 16 Dr. Dunn, there was a change made in the 17 17 becomes embrittled, as you've described it? antioxidant levels, and we were trying to find 18 A. I'm not aware of a published study 18 additional documents to explain that change, 19 that's shown that. But, then again, Ethicon's 19 why it was made. And I don't believe that was 20 internal study reported that. 20 successful. 21 Q. What have you done to understand the 21 O. (By Mr. Thomas) Is Tab 18 in this 22 circumstances of the study that's in Tab 18 of 22 document the extent of Exhibit 3, the extent of 23 Exhibit 3? 23 your knowledge of what you believe to be 24 A. I've read the study, and then there 24 depletion of the antioxidants in Prolene? Page 67 Page 69 A. This is the only study that I'm aware 1 were some minutes that were issued to schedule 1 2 a meeting to -- I think at the meeting, they 2 of that we found that addressed the antioxidant 3 3 talked about the implications of the study question directly. 4 where they were going to measure -- there was 4 Q. In your review of documents in 5 concern about how deep are these surface 5 connection with this case, are you aware of any 6 6 other documents that you've reviewed which cracks. And I think Dr. Dunn was trying to 7 find additional information, SCM. We couldn't 7 address the depletion of antioxidants in 8 find that information. So this was all we 8 Prolene suture or Prolene mesh? 9 could get on this particular study. 9 A. This is the only one that we could 10 10 find that directly addressed the antioxidant But there was a follow-up meeting. 11 We have some minutes from that, but we don't question, how much antioxidant is left. 11 12 have much additional -- they measured some 12 Q. So if I'm going to ask you the 13 crack depths. But I believe it was the SCM 13 question on what documents you rely to support 14 images that we didn't have. We have FTIR data 14 your opinion that the antioxidants in Prolene 15 here for no SCM. 15 suture are depleted over time, you would point 16 Q. Okay. Is it your opinion that the 16 to Tab 18 in Exhibit 3? 17 DLTDP is the only antioxidant in Prolene? 17 A. Well, there's indirect information in 18 MR. JACKSON: Objection to form. 18 the dog study because the dog study observed 19 A. Well, I think I've already answered 19 surface cracking that would also be a 20 that. In 1987, this report refers to the DLTDP 20 consequence of oxidative degradation and 21 stabilizer antioxidant. I can't remember what's 21 embrittlement. But they didn't -- I don't 22 used today. I know there was a range of doses 22 believe in this study they actually looked at 23 23 in the material. That range is pretty broad. the amount of antioxidant remaining.

18 (Pages 66 to 69)

Q. Anything else?

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24

But I don't remember what the current

Page 70 Page 72 A. Those are the two studies that I'm 1 1 discussed the Anderson article. Let me hand 2 aware of that looked specifically at this 2 you what I've marked as deposition Exhibit 3 3 question. No. 6 and ask you if Exhibit No. 6 is the 4 Q. Let's go back to your report on page 4 Anderson study to which you've cited in your 5 4 again. In the middle of the second 5 paper. 6 paragraph, it says, Nor is this stabilization 6 A. Yes. 7 7 permanent. The purpose of using antioxidants Q. And I believe I heard you say that is to react with any oxidated species that you cite Anderson for the proposition that over 8 8 9 threaten the molecular structure of the 9 the life of the material, that antioxidants polypropylene chain. You cite to footnote 4, 10 will be depleted. Did I hear that correctly? 10 MR. JACKSON: Object to the form. 11 but there's no footnote 4. 11 12 12 A. I'm not sure what happened there. It A. I think what I said was this foreign body reaction will continue as long as the 13 must be an oversight. 13 Q. Do you recall the paper upon which 14 14 material was present. 15 you relied for that statement? 15 Q. (By Mr. Thomas) Okay. Does the 16 A. I don't recall the paper for that 16 Anderson article speak to the issue of the one. But I think the point of this statement extent to which antioxidants added to 17 17 18 is really in my experience, antioxidants are polypropylene will be depleted over time? 18 19 added to protect for a certain shelf life. So 19 A. Not directly. I was using Anderson you would add an antioxidant to protect a 20 to support the notion that the foreign body 20 21 polymer for a three-year shelf life. 21 response is ongoing. 22 These types of studies can be done in 22 Q. Are there any of the studies that 23 the known. That type of dosing can be done. 23 you've cited in your report, Exhibit No. 1, What I'm saying is that trying to determine the that support the proposition that antioxidants 24 24 Page 71 Page 73 dosing to protect against in vivo degradation added to polypropylene deplete over time and 1 1 2 is another question. 2 create a risk of degradation? 3 Q. Let me ask you this question: Is it 3 A. As I said before, the only study that 4 your belief that the antioxidants that are 4 looked at specific questions of antioxidant 5 added to Ethicon prolene polypropylene are 5 loss would be the human explants from 1987. Q. That's Tab 18 in Exhibit No. 3? 6 merely for shelf life consideration? 6 7 A. There was a statement that I read in 7 A. Yes. 8 one of the documents. I can't remember which 8 (Exhibit 7 was marked.) 9 one it was. But there was an Ethicon document 9 Q. (By Mr. Thomas) Let me show you 10 that made the statement that the stabilizer was 10 what's been marked as deposition Exhibit No. 7. 11 added to protect against mechanical and thermal Deposition Exhibit No. 7 is a study, 1976, 11 12 12 titled Subcutaneous Implants of Polypropylene processing. 13 Q. Is it your opinion that the 13 Filaments, lead author Liebert. You cite this antioxidants added to Prolene polypropylene are 14 14 in your paper, don't you? 15 only to extend the shelf life of that product? 15 A. Yes. 16 A. The only evidence I have for the 16 Q. This is a 1976 study that compares 17 purpose of adding antioxidants was to stabilize polypropylene implanted in animals with 17 it against manufacturing shelf life in the box antioxidants and without antioxidants; correct? 18 18 before it's implanted. I didn't see any 19 19 A. Yes. 20 evidence in the documents that I reviewed where 20 Q. The Liebert study finds that the polypropylene treated with antioxidants does 21 antioxidants were added dosed for the purposes 21 22 of in vivo stability. 22 not degrade? 23 (Exhibit 6 was marked.) 23 A. In this particular study in this 24 Q. (By Mr. Thomas) A minute ago, you 24 implantation site for this period of time, they

Scott A. Guelcher, Ph.D. Page 74 Page 76 1 were able to protect it from degradation. Let 1 So I see this study as being 2 me look -- I need to look at this for a minute. 2 consistent with Liebert. I think Liebert was 3 So they went out to an implantation 3 asking a different question. I think Liebert 4 time of 160 days. I think that's five or six 4 was saying, Well, for five months, I can add 5 5 enough antioxidant to stabilize the months. 6 So I'm not saying that you can't 6 polypropylene. So I want to compare stabilized protect it for a period of time. I mean, even 7 polypropylene -- it's like a control -- versus 7 unstabilized polypropylene. 8 the human explants showed some antioxidant 8 9 after eight years. I'm saying it's reduced. 9 So Liebert was going after a 10 10 So this is five months. But if you go out different question, but he just didn't go out years, these devices are made to be implanted as far as this study did. So I don't really 11 11 12 in humans for their lifetime. 12 see any consistencies between these two 13 If you go out for very long periods 13 studies. of time, I don't think you can guarantee that 14 14 Q. Are you aware of any studies in the 15 these antioxidants -- they didn't even measure 15 peer-reviewed literature that support your 16 the anti -- I don't think they did. I would 16 position that stabilizers used to protect 17 against oxidation in polypropylene deplete over 17 have to look at it again. time and create a risk of the oxidative 18 So I'm not saying that you can't 18 19 protect it for some period of time. I'm just 19 degradation of polypropylene? saying that I doubt whether you can protect it 20 20 A. There's no studies that have over the lifetime of the device on every 21 21 specifically shown that. But I think from what patient, that you can protect it from 22 we know about the foreign body response, that 22 23 oxidation. This is only five months. 23 the oxidative attack is continuous and ongoing. 24 24 What we know from the human explants, At eight years in these sutures Page 75 Page 77 explanted from humans, they saw loss of 1 1 initially that antioxidant is going to be 2 antioxidant. 2 depleted. That's what I think we know. 3 Q. We know from your earlier testimony 3 Q. When you talk about the sutures at eight years, again, you're talking about Tab 18 4 that polypropylene has been used in tissue 4 in Exhibit 3 of your rebuttal report? 5 5 repair for 50 years now; correct? 6 A. Yes. 6 A. Yes. 7 Q. So you would suggest that Tab 18 of 7 Q. Wouldn't you expect that to be an Exhibit 3, the suture study, is inconsistent 8 issue of significance in the medical and 8 9 scientific literature if polypropylene used for 9 with the findings in Exhibit 7 in Liebert? 10 the last 15 years loses antioxidants and poses 10 A. No. I think they're consistent. Liebert only went out five months. What this a risk to the patients? 11 11 12 A. I don't know if -- the papers I'm 12 study is saying -- let me read the findings 13 13 actually familiar with that I reviewed are not again. 14 specifically looking at the question of Q. Just for your benefit, I don't have 14 15 antioxidant depletion, but they do show signs 15 that study. 16 of oxidation. 16 A. I understand. 17 So if there's signs of oxidation, 17 O. I'll get that, but I don't have that. 18 this study confirms it. And you would 18 A. I understand that. But what this

20 (Pages 74 to 77)

anticipate that if it's oxidizing, the

A. Well, they tested it here.

Q. That's something that could be

Q. You're talking about the Ethicon --

antioxidant is not protecting it.

tested, though, couldn't it?

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study is saying is -- I need to find it.

off, they didn't find it.

So the DLTDP appears reduced at two

years. Two years is longer than five months.

And at eight years, it's further reduced. And

then in the oxidized material that they scraped

Page 78 Page 80 1 A. In the human explants, yeah. 1 stable. But the polyethers are known to undergo 2 Q. I'm talking about in the peer-2 oxidative degradation. 3 3 reviewed literature to the extent that was a Q. Is there any material of which you're 4 phenomenon going on, that was something that 4 aware that you could use for a medical device 5 could be presented in a controlled scientific 5 implant that is not subject to oxidative 6 test that could be subject to peer-review and 6 degradation? 7 7 published in the literature? A. Every material is going to -- the 8 A. They should be able to do that. 8 foreign body response is going to happen when 9 9 you implant a foreign material. So the That's just not what those studies did. They 10 10 were looking more at signs of surface oxidation difference is materials -- materials respond 11 like Liebert did. They were looking at the 11 differently to that foreign body reaction. And 12 phenomenon of surface oxidation. 12 I think Ethicon's data points to polymers like 13 Q. The Anderson paper that we just 13 PVDF as being more resistant to oxidative 14 discussed, the Anderson paper you've cited for 14 degradation. So some are more resistant than 15 the proposition of the continuous foreign body 15 others. 16 reaction to the life of the explant; is that 16 Q. Are you saying that PVDF does not degrade by oxidation in vivo? 17 fair? 17 18 A. What I'm saying is, in the dog study, 18 A. Yes. 19 Q. Any other purpose? 19 the PVDF sutures didn't show evidence of 20 A. General background on the nature of 20 surface cracking. Now, whether there's the inflammatory response that was in the 21 21 oxidative degradation, you would have to use 22 more sensitive techniques like XPS to actually 22 report. 23 Q. Dr. Guelcher, your education is what? 23 characterize a surface. A. So I have a bachelor's degree and 24 24 At seven years in this dog study, Page 79 Page 81 they were not seeing the same amount of 1 master's degree and Ph.D. in chemical 1 2 engineering. 2 cracking that they saw in the polypropylene. 3 3 Q. Do you have an opinion, Dr. Guelcher, Q. And you've not studied polypropylene 4 before your work in this case; correct? 4 that there's any polymer that can be implanted 5 5 A. No. But I've studied oxidative in the human body that is not subject to 6 6 degradation of other polymers. oxidative degradation? 7 Q. And polyurethane is an issue of your 7 A. That's not really within the scope of 8 8 my report. I mean, my report is focusing on interest? 9 A. Yes. 9 oxidative degradation of polypropylene. I'm 10 Q. Does polyurethane degrade in vivo? 10 just noting observations that there are 11 A. Polyurethane is a broad term. So 11 polymers that appear to undergo less oxidative part of my research, we design lysine-derived 12 12 degradation. 13 polyurethane grafts that we published a couple 13 Q. Whether it's in the scope of your 14 14 of papers reporting that they undergo oxidative report or not, do you have an opinion in that 15 degradation. But those polymers are the tissue 15 regard? 16 grafts, so they're designed to degrade 16 A. I have an opinion that some materials 17 oxidatively. 17 are going to degrade more slowly in response to 18 The other side would be biostable 18 that foreign body reaction than others. But I 19 polyurethane implants. They are designed to be 19 don't know that it's been shown conclusively 20 be biostable. Jim Anderson did a lot of work 20 that they do or don't. The data aren't there. 21 over the years investigating the oxidative 21 Q. So is it fair to understand that you 22 degradation of polyether urethanes. So other 22 do not have an opinion as to whether there's 23 materials such as polycarbonate urethanes have 23 any polymer that's available for implantation

21 (Pages 78 to 81)

as a medical device that does not undergo

24

24

have been studied that are more exidatively

Page 82 Page 84 1 oxidative degradation? 1 is relatively -- it's a very small slope. 2 A. I mean, I wouldn't say does not. I 2 And then at some point when that 3 would just say it's much more stable than 3 induction time is reached, it becomes 4 polypropylene. There are polymers that are 4 autocatalytic, and the concentration of those 5 more oxidatively stable than polypropylene. 5 groups increases. 6 O. What are those? 6 What Fayolle is saying is that 7 7 A. Well, the PVDF and -critical molecular weight for embrittlement in 8 Q. What else? We've talked about PVDF. 8 the materials he looked at, he was reporting a 9 9 molecular weight of 200,000 grams per mole. Anything else? 10 10 A. What else did I look at? I said And he noted that that embrittlement on the 11 polycarbonate urethanes are more stable 11 basis of mechanical testing, that embrittlement 12 against oxidative degradation than polyethers. 12 is happening prior to the induction time 13 Those would be a few. 13 measured by spectroscopy. 14 Again, I'm not -- I'm focusing in my 14 Q. I'm going to need you to help me 15 report my opinions on that polypropylene 15 understand these charts. 16 degrades oxidatively in a significant rate. 16 A. Okay. We're on page 5 now of Exhibit No. 1. 17 Q. Going back to your report, page 4, 17 note 4, do you know what site is appropriate 18 A. Right. 18 19 there that is left out in footnote 4? 19 Q. And these are charts that you 20 borrowed from Dr. Fayolle's paper? 20 A. I don't. I don't have that with me. A. They were published in the Fayolle 21 Q. The next paragraph says, The 21 22 study from 2000. 22 oxidation of the polymer on the tertiary 23 hydrogen bond is the rate controlling step in 23 Q. At the top of (a), it says this process, and it will result in the 24 24 spectrophotometric induction time. What does Page 83 Page 85 polypropylene's molecular chain being broken 1 1 that mean? 2 and the reaction repeating until no more 2 A. The spectrophotometric induction time 3 polypropylene can be broken down. What does 3 is the time at which there's that change in the 4 that mean? 4 slope of concentration of hydroxyle groups and 5 5 A. I think that statement is referring carbonyl groups. So that line is almost flat, б 6 so there's very small change. to this autocatalytic effect. Once you start 7 to form these reactive species on the surface, 7 And then at some point, it becomes 8 it just continues to react. There's no reason 8 autocatalytic. The concentration of these 9 for it to stop. It will continue to react and 9 groups on the surface is high enough that now 10 in later stages of degradation, there could be 10 the rate at which the oxidation reaction is 11 molecular weight loss and embrittlement. 11 happening is much faster. That's the induction 12 Q. At what stage would there be 12 time. 13 molecular weight loss? 13 Q. Just for my benefit, the 14 A. That's addressed by this concept of 14 spectrophotometric induction time is represented in figure A as the triangles and 15 the induction time. So the paper by Fayolle 15 16 and Liebert, these papers together are 16 squares at the bottom? 17 suggesting -- there's a -- Fayolle put out the 17 A. Yes. 18 notion that embrittlement can happen -- this is 18 Q. And so at the point at about, oh, 250 19 in figure 1. 19 to 260 is where there's a change in the 20 So the induction time that's measured 20 hydroxyle groups and carbonyl groups which 21 by, in this case, the FTIR measurements, the 21 reflects a chemical change in the 22 induction time is where there's this sharp 22 polypropylene? 23 change in the slope of the curve. So the 23 A. That's right. 24 concentration of hydroxyle and carbonyl groups 24 Q. So the embrittlement induction time

Page 88 Page 86 1 means what? 1 there. 2 A. This is a nice part of the work that 2 These concepts of tie chains and 3 3 Fayolle did. He was measuring ultimate amorphous chains that connect crystalline 4 elongation here by this. So embrittlement 4 regions are breaking and that can lead to 5 induction time, that's where the axis on the 5 embrittlement. So what Fayolle is saying is 6 left with the curves with the hash lines, as you 6 that changes in the polymer that lead to 7 can see, the elongation is relatively constant. 7 embrittlement happen before large 8 Then when you reach this embrittlement 8 concentrations of hydroxyle and carbonyl 9 induction time, the material becomes highly 9 groups, which has been the traditional way. 10 brittle and less elongation. 10 Even XPS would measure formation of hydroxyle 11 Q. What does elongation mean? 11 and carbonyl groups on the surface. 12 A. That's the amount that you can 12 What Fayolle is saying is that 13 stretch it. Out here, it's 800 percent. You 13 embrittlement happens you can really -- before 14 can stretch it to eight times its initial 14 that becomes appreciable. It becomes this 15 length. When it becomes brittle, that number 15 autocatalytic increase. 16 drops below -- then even small amounts of 16 Q. Now, figure B uses axes of molecular 17 strain cause the material to fail. weight, time, and concentration moles per 17 18 Q. Now, is it fair to understand --18 kilogram; correct? 19 again, me trying to understand this chart --19 A. Yes. 20 that at the beginning of the study, the range 2.0 Q. Is B appropriate to overlay on A? 21 of the elongation is around 750 to 900? 21 A. So my comments, my notations, on 22 A. Right. 2.2 Panel B were designed to kind of interpret A 23 Q. And then over time, it decreases and 23 especially in light of Liebert. 24 then drops off rather dramatically at about 125 24 So Fayolle reports a critical Page 87 Page 89 1 to 175 hours. Am I reading that correctly? 1 molecular weight for embrittlement in the 2 A. Yes. 2 polymers he was looking at 200,000 grams per 3 3 Q. So after that period of time, you mole. The polypropylene samples he was using 4 became embrittled when the molecular weight have a reduction in elongation and increase in 4 5 5 embrittlement. And then about 75 hours later, dropped to 200,000 grams per mole. That's what 6 6 that critical molecular weight -- that's what you have an increase in the hydroxyle and the 7 7 carbonyl groups. Is that fair? Fayolle was saying. 8 A. That's right. 8 Q. It starts at about 225,000? 9 Q. Each one of these changes that are 9 A. That's when the material becomes 10 10 sufficiently brittle that it's -- the material shown in Exhibit A amount to a change in the is basically brittle. 11 chemical structure of the polypropylene; 11 correct? 12 Q. This shows the change in molecular 12 13 A. Well, the hydroxyle and carbonyl 13 weight over time? 14 groups, that's the introduction of bound A. Yes. 14 15 oxygen. The embrittlement is a mechanical 15 Q. And at about 210 hours is when you 16 property. That's not a -- the structure of the 16 reach a reduction in molecular weight from 17 polymer is changing. It's becoming brittle. 17 about 260 to about 200,000? 18 18 A. That's how Fayolle defined it, as Q. But the chemical structure of the 19 polymer does not change in figure A until you 19 embrittlement at that 200,000 molecular weight. 20 get to the formation of the hydroxyle groups 20 Q. The molecular weight then continues 21 and the carbonyl groups? 21 to become reduced until at about 260 hours the 22 A. The chemical structure is breaking, 22 molecular weight of the polypropylene or 23 and Fayolle explains the details. And there's 23 whatever substance you're measuring at that 24 some explanations for what could be happening 24 point is down around 75,000; correct?

Page 90 Page 92 1 A. That's right. 1 pull together the auto-oxidation that's 2 Q. Now, the hydroxyle group and the 2 observed in air at elevated temperatures with 3 carbonyl groups are the same graphs that are on 3 what happens in the body. It's just a 4 figure A; correct? 4 different source of oxygen, reactive oxygen in 5 A. Yes. 5 the body. Q. So at the bottom where you have time 6 6 Q. So in the Fayolle part of figure B on 7 and days and subcutaneous implantation, what 7 page 5 where it shows at 210 hours there's the 8 does that mean? 8 critical molecular weight for embrittlement, 9 9 you drop down and get at about 90 days. How do A. So I added the line -- the red line 10 at the bottom is a way to interpret the data 10 those two -- 210 hours, which is less than ten 11 from Liebert. So what Liebert was teaching was 11 days, and 90 days -- how can you draw those 12 that -- he reported an induction time of 108 12 together? 13 13 days by his own -- he did very similar measures A. Well, that's what I was saying. So 14 on explanted materials of hydroxyl and carbonyl 14 the hours axis is that's the auto-oxidation 15 groups. 15 that just happens with molecular oxygen as an 16 16 And he reported in vivo induction oxygen source at elevated temperatures. 17 17 time of 108 days. And then he notes if you What Liebert is saying is this 18 consider molecular oxygen as the source and 18 process happens over this time of about 100 19 physiological temperatures, there should be an 19 days in vivo because there's a different source 20 20 induction time of 20 years, and yet we're of reactive oxygen. It's the reactive oxygen 21 21 measuring 108 days. Clearly, there has to be species secreted by the inflammatory cells. 22 some sort of reactive oxygen within the body. 2.2 That's why -- that's the difference in the time 23 Based on the work of Anderson and 23 scale. 24 others, we know now that that's associated with 2.4 Q. Okay. And so the time scale for Page 91 Page 93 the foreign body response. That's where the Liebert, where you say that the embrittlement 1 2 208 days come from. That's the induction time 2 will occur at about 90 days, is based upon 3 measured by Liebert for unstabilized 3 Liebert's study of polypropylene without 4 polypropylene explanted from the sutures in the antioxidants? 5 5 films -- explanted from the hamsters. A. Right. 6 So the 90 days is an approximation of 6 Q. And the Fayolle study is based upon 7 this concept of Fayolle that it basically 7 testing of polypropylene with the antioxidants 8 becomes embrittled before this induction time, 8 removed; correct? 9 and he's basically saying -- you can deduce 9 A. Let me look at the Fayolle study 10 from this as around 90 or a hundred days it's 10 again to make sure. 11 becoming embrittled, unstabilized polypropylene 11 Q. Do you recall that without looking? 12 in vivo. That's what this is saying. 12 A. Let me look at it for a minute. 13 Q. And figure A is all Fayolle; correct? 13 Q. I have it for you here if that's A. Both of those plots, the plots 14 14 easier. A. I've got it. 15 themselves came from Fayolle. Everything in 15 16 black came from Fayolle. 16 MR. THOMAS: Let me mark it anyway as 17 17 a deposition exhibit. It's deposition Q. All I have is black and white. 18 A. All right. So I used a different 18 Exhibit 8, a copy of the Fayolle study. 19 font. You can probably tell a difference in 19 (Exhibit 8 was marked.) 20 the fonts that I used. 20 Q. (By Mr. Thomas) Exhibit 8 is a study 21 Q. The time (days) subcutaneous 21 titled Oxidation Induced Embrittlement in 22 implantation, where does that come from? 22 Polypropylene, a tensile testing study June 23 A. That is the time scale that Liebert 23 2000 by B. Fayolle, F-a-y-o-l-l-e. 24 measured. So what this plot is trying to do is 24 A. So he says in the experimental

	Page 94		Page 96
1	section, The additives, I'm presuming the	1	discussed on page 5 of your report, to your
2	stabilizers, antioxidants were extracted in a	2	knowledge, this type of analysis has not been
3	soxhlet extractor in chloroform hexane ethanol.	3	done for polypropylene with antioxidant
4	I would interpret that statement as saying	4	packages?
5	that there was also unstabilized polypropylene.	5	MR. JACKSON: Objection to form.
6	Q. Have you seen any testing of	6	A. I don't know that this particular
7	stabilized polypropylene to support the	7	test has been done for polypropylene with the
8	positions that you take on page 5 of Exhibit	8	antioxidant.
9	No. 1?	9	Q. Okay. Now, the Fayolle paper,
10	A. No. These data were the data that I	10	Exhibit No. 8, also deals with thermal
11	had for unstabilized polypropylene.	11	oxidation of polypropylene films. Do you see
12	Q. Let's take a quick break please.	12	that?
13	(A break was taken from 11:31 a.m. to	13	A. Yes.
14	11:41 a.m.)	14	Q. Does the fact that they're testing
15	Q. (By Mr. Thomas) Let's go back to	15	polypropylene films as opposed to polypropylene
16	page 5 of Exhibit No. 1. Is it fair to	16	sutures or mesh have any impact on your
17	understand, based upon your analysis of Liebert	17	opinions?
18	and Fayolle as depicted in these two graphs on		*
19	page 5, that there is no embrittlement without	18	A. Let me look at this for just a minute.
20	a loss of molecular weight?	19	
21	A. I don't know that I would say it that	20	I'm just looking to see if he they
22	way. I would say that loss in molecular weight	21	don't report film thicknesses.
23	leads to embrittlement.	22	Q. Look at the very beginning in the
24		23	abstract. They talk about a hundred microns.
24	Q. Okay. The tests that we've just	24	Is that the thickness of the film?
	Page 95		Page 97
1	discussed strike that. The papers that	1	A. Okay. Yeah. I see a hundred
2	we've just discussed by Fayolle and Liebert	2	microns. For some reason it's not in the
3	where you used test data from polypropylene	3	experimental.
4	without antioxidants, these same tests could be	4	So my why I believe they used
5	used for testing polypropylene with	5	hundred micron films is because these films are
6	antioxidants, couldn't they?	6	very thin. So because they're so thin, these
7	A. These tests?	7	changes in the surface are going to result in
8	Q. Yes.	8	molecular weight degradation because the
9	A. Yes. You have to go out to longer	9	sutures are much thicker. So they're on the
10	time points, but they could be used.	10	millimeter scale.
11	Q. Right. And to your knowledge, none	11	Basically, because they're using
12	of that testing has been done?	12	these thin films, that allows them to measure
13	A. Not using this specific approach. I	13	these changes in molecular weight more
14	mean, there are papers where people have looked	14	accurately, because molecular weight is a
15	at explants and noted evidence of surface	15	volume average property. So if you use a very
16	oxidation, but not this type of time course. A	16	thin film, then surface degradation is going to
17	mechanistic study that would have to be done	17	contribute more to molecular weight loss of the
18	in vitro.	18	bulk polymer.
19	Q. The studies that you're referring to	19	Q. How big are sutures, did you say?
20	are the Clave and Costello articles that you	20	A. Three or five let me just look.
21	referred to elsewhere in your report?	21	It was in one of these studies. Let me find
22	A. Yes.	22	it. I thought it was. I can't seem to find
23	Q. But in terms of the types of studies	23	it.
24	conducted by Liebert and by Fayolle that are	24	Q. It's not really important to my

1	Page 98		Page 100
	question.	1	that you conducted yourself; true?
2	A. Okay.	2	A. Yes. These are literature data. As
3	Q. Is there a difference between the use	3	I said earlier, we didn't even have materials
4	of a film and the use of a suture for purposes	4	to test for this sort of work.
5	of this analysis done by Fayolle?	5	Q. Paragraph 2 on page 6 titled
6	A. You would see the same changes on the	6	Polypropylene Degradation In Vivo, the second
7	surface of a suture that you would see on the	7	full paragraph says, Macrophages and FBGCs
8	surface of a film. But you might not see the	8	attached to biomaterials are known to lead to
9	same changes in molecular weight because with	9	degradation and device failure.
10	the film, the surface is a larger well,	10	There's no cite there. Do you know
11	okay.	11	what cite is appropriate there?
12	Q. The oxidation that Fayolle studies is	12	A. Which paragraph is this again?
13	thermal oxidation, isn't it?	13	Q. Right in the middle of the page,
14	A. It's thermal oxidation. That was the	14	adhesion of macrophages. The last sentence
15	point of figure 1 in my report of page 5 was to	15	reads, Macrophages and FBGCs attached to
16	connect the time scales. What Liebert was	16	biomaterials are known to lead to degradation
17	saying is thermal oxidation under physiological	17	and device failure?
18	conditions, molecular oxygen, 37 c. would take	18	A. I believe Anderson discusses this
19	20 years, but he observes 108 days. That	19	point. In my own research, we've shown that
20	points to a much more reactive source of oxygen	20	macrophages attached to the scaffolds lead to
21	in the body.	21	active degradation. We published that in 2011.
22	So they're similar processes. It's	22	Q. With what material?
23	just the difference in the source of the	23	A. With the polyurethane.
24	oxygen. Fayolle was looking at sort of	24	Q. Have you found any kind of literature
	Page 00		Davis 101
	Page 99		Page 101
1	thermally-induced where you heat it up, and	1	which supports the proposition that macrophages
2	molecular oxygen is actually the source of		IEDGG # 1 1 1 1 1
٦ .		2	and FBGCs attached to polypropylene are known
3	oxygen that causes reaction.	3	to lead to degradation and device failure?
4	oxygen that causes reaction.  Q. Thermal oxidation, is at 90 degrees	3 4	to lead to degradation and device failure?  A. Well, some of the clinical studies
4 5	oxygen that causes reaction.  Q. Thermal oxidation, is at 90 degrees c.?	3 4 5	to lead to degradation and device failure?  A. Well, some of the clinical studies report the presence of an inflammatory
4 5 6	oxygen that causes reaction. Q. Thermal oxidation, is at 90 degrees c.? A. I don't know what temperature he	3 4 5 6	to lead to degradation and device failure?  A. Well, some of the clinical studies report the presence of an inflammatory infiltrate in these cells, and some of these
4 5 6 7	oxygen that causes reaction.  Q. Thermal oxidation, is at 90 degrees c.?  A. I don't know what temperature he used.	3 4 5 6 7	to lead to degradation and device failure?  A. Well, some of the clinical studies report the presence of an inflammatory infiltrate in these cells, and some of these materials extruded or became affected.
4 5 6 7 8	oxygen that causes reaction.  Q. Thermal oxidation, is at 90 degrees c.?  A. I don't know what temperature he used.  Q. First page of the abstract.	3 4 5 6 7 8	to lead to degradation and device failure?  A. Well, some of the clinical studies report the presence of an inflammatory infiltrate in these cells, and some of these materials extruded or became affected.  Q. My question is simpler than that. My
4 5 6 7 8 9	oxygen that causes reaction.  Q. Thermal oxidation, is at 90 degrees c.?  A. I don't know what temperature he used.  Q. First page of the abstract.  A. 90 c.	3 4 5 6 7 8 9	to lead to degradation and device failure?  A. Well, some of the clinical studies report the presence of an inflammatory infiltrate in these cells, and some of these materials extruded or became affected.  Q. My question is simpler than that. My question is whether you're aware of any peer-
4 5 6 7 8 9	oxygen that causes reaction. Q. Thermal oxidation, is at 90 degrees c.? A. I don't know what temperature he used. Q. First page of the abstract. A. 90 c. Q. And normal body temperature is 37 c.?	3 4 5 6 7 8 9	to lead to degradation and device failure?  A. Well, some of the clinical studies report the presence of an inflammatory infiltrate in these cells, and some of these materials extruded or became affected.  Q. My question is simpler than that. My question is whether you're aware of any peer-reviewed literature which finds that
4 5 6 7 8 9 10	oxygen that causes reaction. Q. Thermal oxidation, is at 90 degrees c.? A. I don't know what temperature he used. Q. First page of the abstract. A. 90 c. Q. And normal body temperature is 37 c.? A. Yeah. But I was saying that Liebert	3 4 5 6 7 8 9 10 11	to lead to degradation and device failure?  A. Well, some of the clinical studies report the presence of an inflammatory infiltrate in these cells, and some of these materials extruded or became affected.  Q. My question is simpler than that. My question is whether you're aware of any peer-reviewed literature which finds that macrophages and FBGCs attached to polypropylene
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Page 102 Page 104 1 that. 1 And many of those explants, he saw inflammatory 2 O. Is it true? 2 reactions associated with infection or a 3 A. I'm going to stick by my answer. 3 chronic inflammatory response. 4 There are inflammatory cells present, and he's 4 He saw cracking on the surface which 5 explaining samples that failed. 5 is consistent with oxidative degradation as 6 Q. Is there any report in the peer-6 even pointed out in Ethicon's studies, the dog 7 7 reviewed literature that any polypropylene mesh study and the human explants. 8 or suture failed due to macrophages and FBGCs 8 He sees evidence by FTIR of carbonyl 9 attaching to polypropylene? 9 groups that are associated with oxidative 10 A. Let me look at Clave again. 10 degradation. Now he comments that he can't say 11 (Exhibit 9 was marked.) 11 whether it's oxidative degradation or whether 12 Q. (By Mr. Thomas) For the record, 12 it's something else, but it's consistent with you're referring to Exhibit No. 9, which is the 13 13 the notion of oxidative degradation. 14 Clave article. So Clave reports two types of 14 So when you take Clave plus Ethicon's 15 responses, a Type 1 and a Type 2 reaction 15 own data that oxidation can lead to surface 16 characteristic of an infection. A majority 16 cracking and embrittlement, I think Clave is 17 of altered polymorphonuclear neutrophils 17 teaching that meshes that were explanted 18 were found; suggested an infectious process. because of complications because they failed 18 19 This is on page 263 under the histological 19 showed this inflammatory response and surface 20 analysis. 20 oxidation. That's the way that I would answer 21 He also reports a Type 2 reaction is 21 your question. 22 chronic inflammation rich in giant cells and 2.2 Q. Is Clave the only support that you 23 mononuclear cells. And then he also sees 23 have that macrophages and FBGCs attached to 24 these -- evidence of what could be oxidative biomaterials are known to lead to degradation 24 Page 103 Page 105 degradation. He sees evidence of cracking. 1 and device failure? 2 These are basically supporting his 2 A. Let me look at Costello as well. 3 conclusions that these polypropylene implants 3 Q. Is Costello the only other one that 4 are altered in vivo. 4 you would look to? That's not an Ethicon mesh, 5 Q. \* But there's nothing in Clave's 5 by the way, is it? 6 article, Exhibit No. 9, that discusses device 6 A. No. But it does have a polypropylene 7 7 component, I believe. failure, is there? 8 8 A. Let me read what he wrote again. Q. Does it have a polypropylene 9 Well, I mean, these are a hundred implants, 9 component with the Ethicon added effect? 10 explanted from patients due to complications. 10 A. I don't know. Let me just see what 11 So I would say that the device failed if they 11 he says. Yeah, these were the Bard 12 had to take it out because of complications. 12 composites. But he discusses oxidation. He 13 Q. When you're talking about 13 has some SCM images showing surface effects, degradation, you're talking about the 14 14 effects of surface oxidation. 15 polypropylene being degraded to the point where 15 Q. You're in the Costello study now? 16 it breaks or fails; correct? 16 17 17 A. No. I think that's discussed in my Q. Is polypropylene ever appropriate to use in a medical device? 18 report, is where you have surface oxidation 18 19 that can lead to molecular weight loss, 19 MR. JACKSON: Objection to form. 20 embrittlement, cracking, is a whole chain of 20 A. I'm not really here to speak to that. 21 events that happens. 21 I was looking at suitability for polypropylene 22 What I'm saying is that Clave took a 22 in these pelvic floor-type applications. 23 hundred explants from patients that had 23 Q. (By Mr. Thomas) For the pelvic 24 complications that had problems with the mesh. 24 floor, is polypropylene ever appropriate to use

Page 106 Page 108 1 in a medical device? 1 A. Well, I think that these papers are 2 A. Not saying whether it's appropriate 2 showing there is surface oxidation that we know 3 to use or not. I'm saying that it can undergo 3 leads to embrittlement. Then these devices that 4 surface oxidation due to the foreign body 4 are extruded are infected as a complication. 5 reaction that can lead to changes in the 5 So I think that these papers are 6 polypropylene, and those changes are not fully 6 showing the connection between the two. 7 7 understood. Q. Are there any papers in the medical 8 They're observed by Ethicon in their 8 or scientific literature that suggest that 9 own studies. They were never really followed 9 surface oxidation of polypropylene mesh can 10 up on or understood. And so the long-term 10 lead to extrusion? behavior of the device is unpredictable. I'm 11 11 A. I think Clave is suggesting this, as 12 not saying that it can never be used. I'm 12 I was explaining. He sees these hundred meshes 13 saying because of these changes due to foreign 13 where there were problems. He sees evidence of 14 body reaction, its performance can be 14 surface oxidation. He sees inflammatory cells 15 unpredictable. 15 and the infiltrate infection. 16 Q. You say it's unpredictable. Does 16 Q. Is that the sole basis for your that mean you do not have an opinion as to what 17 17 opinion that surface oxidation of polypropylene 18 will happen to the device over the life of its 18 mesh can lead to extrusions, the Clave article? 19 implantation? 19 A. Clave would probably be the one. 20 A. I believe that over the life of its 20 Q. Anything about your own work that 21 implantation, the polymer will change in you've done in your training, education, and 21 22 response to the foreign body reaction. Well, 22 experience outside of Clave that leads you to 23 specific changes would be loss of molecular 23 conclude that surface oxidation of 24 weight, embrittlement. In some patients, that 24 polypropylene mesh can lead to extrusion? Page 107 Page 109 1 can lead to extrusion, pain. It's consistent A. Not that I'm aware of. 2 with those adverse events in patients. 2 Q. What is the basis for your opinion 3 that surface oxidation on polypropylene mesh 3 And I believe that the instability of 4 the polymer can contribute to those adverse 4 leads to pain? 5 5 A. I think if you have a brittle piece events. 6 6 of plastic embedded in soft tissue, it's going Q. Okay. What is it that allows you to 7 offer the opinion that the surface oxidation of 7 to be painful. 8 polypropylene that you've described leads to 8 Q. Is this based upon what you know or based upon any scientific literature to support 9 extrusions? 9 10 A. Well, I think Ethicon even noted in 10 your position? A. I would have to look for some papers 11 some of their documents the importance of 11 matching the properties of the mesh to the 12 12 on this. But, I mean, I think it's obvious if 13 properties of the host tissue. This is known, 13 you have brittle plastic in your body, it's 14 it's true just -- it's important to match the 14 going to hurt. 15 properties of the implant to that of the 15 Q. It's based on that obviousness as 16 tissue. 16 opposed to your review of any scientific 17 So if you have an implant that now is 17 literature; is that fair? becoming very brittle, it's no longer 18 18 A. I can't think of a paper right now 19 comparable to the tissue that it's surrounded 19 that explicitly says that. 20 20 Q. Just so we understand, you don't know 21 Q. Is this something you're just 21 whether the mesh in Ms. Edwards was brittle, do deducing and piecing together or something 22 you, to use the term as you've used it? 22 that's based upon any kind of medicine or 23 MS. LEWIS: Objection: Form. 23 24 science? 24 A. We didn't have an opportunity to

28 (Pages 106 to 109)

	Page 110		Page 112
1	measure that.	1	brittle material would not be very tough
2	Q. (By Mr. Thomas) The same is true	2	because if you take it out to small strains, it
3	with the mesh of Ms. Edwards, you don't have	3	fails.
4	any idea whether the mesh in Ms. Edwards was	4	Q. Okay. Do you know whether Ethicon
5	brittle, using the term as you've used it?	5	Prolene after implantation is more or less
6	MS. LEWIS: Objection: Form.	6	tough after seven years?
7	MR. JACKSON: I'm going to object	7	MR. JACKSON: Object to the form.
8	too. You brought two names in there.	8	A. Well, I think that question is rather
9	MR. THOMAS: Let me start over again.	9	complicated. Let me find the data.
10	I want to get a clean question.	10	Q. (By Mr. Thomas) Are you looking in
11	Q. (By Mr. Thomas) It's fair to	11	the seven-year dog study now?
12	understand, Dr. Guelcher, that you don't know	12	A. Yes. I'm trying to find the data. I
13	whether the mesh in Ms. Huskey was brittle	13	don't know. I'm not finding the data here.
14	using the term as you've used it here today.	14	Q. Do you have a recollection of looking
15	MR. JACKSON: Object to the form.	15	at the toughness data in the Ethicon studies?
16	A. Without the explant materials, we	16	A. From what I remember, there was the
17	couldn't do that assessment.	17	elongation was either the same after a year or
18	Q. It's fair to understand that you	18	even got a little worse after two years. And
19	don't know as you sit here today whether the	19	all of a sudden in seven years, it becomes much
20	mesh in Ms. Edwards was brittle using that term	20	more ductile.
21	as you've used it here today?	21	So I had questions about the
22	MS. LEWIS: Objection: Form.	22	methodology used to do those measurements. All
23	A. Without the explants, we can't do the	23	the materials that were tested showed that same
24	measurement.	24	trend. All four of them, the Ethilon, Novafil,
			· · · · · · · · · · · · · · · · · · ·
	Page 111		- 440
	rage III		Page 113
1	Q. (By Mr. Thomas) On page 6 of your	1	Page 113 Prolene, they all showed that same trend.
1 2	Q. (By Mr. Thomas) On page 6 of your report, you again identify examples of	1 2	Prolene, they all showed that same trend.  So this report in the expert report
	Q. (By Mr. Thomas) On page 6 of your		Prolene, they all showed that same trend.  So this report in the expert report focused on seven-year data. But if this were
2	Q. (By Mr. Thomas) On page 6 of your report, you again identify examples of	2	Prolene, they all showed that same trend.  So this report in the expert report
2 3	Q. (By Mr. Thomas) On page 6 of your report, you again identify examples of polyurethanes which have degraded over time.	2 3	Prolene, they all showed that same trend.  So this report in the expert report focused on seven-year data. But if this were
2 3 4	Q. (By Mr. Thomas) On page 6 of your report, you again identify examples of polyurethanes which have degraded over time. Did you try to identify any polypropylene	2 3 4	Prolene, they all showed that same trend.  So this report in the expert report focused on seven-year data. But if this were really going on, why aren't you seeing it in
2 3 4 5	Q. (By Mr. Thomas) On page 6 of your report, you again identify examples of polyurethanes which have degraded over time. Did you try to identify any polypropylene products that had degraded over time that led to device failures?  A. Well, I mean, again, I think Clave	2 3 4 5	Prolene, they all showed that same trend.  So this report in the expert report focused on seven-year data. But if this were really going on, why aren't you seeing it in the one- or two-year data. It just seems strange to me.  Q. Have you seen other studies conducted
2 3 4 5 6	Q. (By Mr. Thomas) On page 6 of your report, you again identify examples of polyurethanes which have degraded over time. Did you try to identify any polypropylene products that had degraded over time that led to device failures?	2 3 4 5 6	Prolene, they all showed that same trend.  So this report in the expert report focused on seven-year data. But if this were really going on, why aren't you seeing it in the one- or two-year data. It just seems strange to me.
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. (By Mr. Thomas) On page 6 of your report, you again identify examples of polyurethanes which have degraded over time. Did you try to identify any polypropylene products that had degraded over time that led to device failures?  A. Well, I mean, again, I think Clave addresses this point of connecting surface degradation with failure of a mesh.  Q. Okay. Other than Clave, did you find any other evidence of device failure using polypropylene?  MR. JACKSON: Object to the form.  A. That's the one I can think of right now.  Q. (By Mr. Thomas) Okay. What is toughness?  MR. JACKSON: Object to the form.  A. Well, toughness is typically associated with the area under the stress/ strain curve.  Q. What does it mean?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Prolene, they all showed that same trend.  So this report in the expert report focused on seven-year data. But if this were really going on, why aren't you seeing it in the one- or two-year data. It just seems strange to me.  Q. Have you seen other studies conducted on Ethicon prolene polypropylene analyzing the extent to which the implanted polypropylene is more tough than the pristine polypropylene.  A. The only data I've seen on Ethicon polypropylene is the dog study where they did mechanical testing on the sutures.  Q. And increased toughness and increased embrittlement are polar opposites of each other; is that fair?  A. Yeah.  Q. And if something became more tough, by definition, it becomes less brittle?  A. But that's if you believe those seven-year data. They seem flawed to me. The methodology in the report is not there's not

	Page 114		Page 116
1	this elongation, this increase in ductility in	1	generates new surface that oxidated species can
2	seven years and one and two years you're not	2	use and cells can migrate into and continue
3	seeing it.	3	this process of oxidative degradation. That's
4	Q. You've not conducted your own tests	4	what that's referring to.
5	to determine whether these polypropylene	5	Q. When you look at, under scan
6	sutures become more tough after implantation,	6	electronic microscopy, environmental stress
7	have you?	7	cracking of these polyurethanes, what do you
8	A. No.	8	see?
9	Q. On page 6 of Exhibit No. 1 in your	9	A. You see cracks in the material. I
10	report, you're talking about failure mechanisms	10	don't know what you mean.
11	that you've observed in connection with	11	Q. Does it flake off? Does it break?
12	polyether urethanes and polyester urethanes.	12	Does it propagate throughout the center of the
13	Do you see that?	13	fiber?
14	A. Yes.	14	MR. JACKSON: Objection to form.
15	Q. Is this work that you've been	15	A. It can. They're not typically
16	involved in?	16	fibers. These are more bulk material.
17	A. So the environmental stress cracking	17	Yeah, pacemaker lead insulation. So
18	of biostable polyether urethanes is primarily	18	it's a different form of the material. It's
19	the work of Dr. Anderson.	19	not necessarily a fiber.
20	Q. Have you done any work in that	20	Q. (By Mr. Thomas) When you have
21	regard?	21	oxidative degradation in the surface of the
22	A. We've done in the papers I've	22	polyurethane in what you mentioned on page 6
23	published, we've shown that these materials	23	of your report, does the material flake off?
24	degrade in vitro they degrade in vivo due to	24	A. It can. I don't know that it always
	Page 115		Page 117
1	oxidative degradation, and they degrade in	1	does. That can be an outcome. Particulates.
2	vitro using a macrophage pocket simulating	2	Q. Does it crack down through the entire
3	fluid developed by Dr. Anderson. We see a	3	body of the implant?
4	connection between those rates of degradation	4	MR. JACKSON: Object to the form.
5	in vitro and in vivo that led us to conclude	5	A. I don't know if it goes through the
6	they're degrading by oxidation.	6	entire body. The surface cracks, and then the
7	Q. Is the mechanism of oxidation that	7	cracks can grow.
8	you've observed in the polyurethanes the same	8	Q. (By Mr. Thomas) Does the material
9	as the mechanism that you've suggested occurs	9	flake off and cleave off so that you have a
10	with polypropylene?	10	smooth surface underneath?
11	MR. JACKSON: Object to the form.	11	A. I don't know. I mean what I'm
12	A. The difference between the two	12	saying here is that it cracks, and then the
13	polymers would be where the oxidative attack	13	cracks generate new surface that can lead to
14	takes place in the chain. So in the	14	more oxidation. If pieces become embrittled,
15	polypropylene, it's the hydrogen on the	15	it can slough off like they saw in the dog study
16	tertiary carbon that's being that	16	or the human explants where you end up with the
17	hydrogen-carbon bond is being attacked.	17	layer of degraded material.
18	Q. (By Mr. Thomas) So the polyether	18	Q. What is crack propagation?
19	urethanes would undergo environmental stress	19	A. If the crack grows.
20	cracking, and then you would have subsequent	20	Q. It's like when you put a crack in a
21	loss of molecular weight?	21	windshield and you press on it, it spreads
22	A. The idea is similar to what we saw in	22	across the windshield? That's crack
23	the SCM images of the cracked polypropylene.	23	propagation?
24	Once the surface starts to crack, that	24	MR. JACKSON: Object to the form.

#### Page 118

A. I think that's a little different. I think crack propagation would be the crack into the surface can deepen. It can widen. Again, once it cracks, there's two things that can happen. It becomes mechanically compromised, and then it generates new surface for oxidative attacks. So the crack can grow and propagate through the material.

- Q. (By Mr. Thomas) In what direction does the crack propagate? Does it matter?
- A. You know, I would think it would be inclined to propagate in the direction of the stress. But it just depends on the loading, on the type of material.
- Q. Something that could be tested, of course?
  - A. I think Ethicon looked at this too.
- Q. I'm talking about you now, whether you could test --
  - A. I haven't done these studies. These are published studies. The materials that I work with are designed to be resorbable, so they don't typically crack. They're resorbed and replaced with new tissues.

#### Page 120

- the fiber length. So they report measurements of crack depth. But there's no pictures. They just report the numbers.
  - These were materials that were implanted anywhere from two to seven and a half years.
  - Q. Is that the only information that you have to look to to determine the extent to which cracks will propagate in polypropylene?
- A. Let me look at the other one, the human explants.
  - Q. That's Tab 18 in Exhibit 3?
- A. Yeah. So, again, they don't provide a lot of details. This is one of the documents Dr. Dunn was trying to get. We don't have SEM images. They have microscopy observations by -- I think this is Mr. Schiller who did SEM.

At two years, he notes no cracking. At eight years, he notes severe cracking. Without the pictures, we don't know what that means. But he basically says that at eight years, they're severely cracked.

So these are the two documents that I'm aware of where Ethicon was looking at

#### Page 119

I haven't actually done experiments of measuring crack propagation.

Q. So you don't know how crack propagation would manifest itself in polypropylene which had undergone surface oxidation?

MR. JACKSON: Object to the form.

- Q. (By Mr. Thomas) Is that fair?
- A. Let me look at this document for a minute.
  - Q. What are you looking at now?
- A. This would be a memo on crack depth in explanted prolene polypropylene sutures.
- Q. This is another document that you've brought here today, Tab 19 in Exhibit No. 3 dated June 15, 1982?
- A. Yes. So in this study, they were measuring the depth of the crack. They concluded that the sutures had crack depths varying from .5 to 2 microns. The diameter of the suture in this case was 25 microns.

Crack depth does not vary systematically with implantation time. It varies significantly from point to point along Page 121

- cracking of polypropylene sutures.
- Q. My question, Doctor, are those two documents, 18 and 19 in Exhibit No. 3, the sole source of your understanding of what happens to polypropylene when there's cracking?
  - A. Well, I think Clave also addressed this, that cracking was associated with these failed meshes that were either infected or extruded or had other complications.
- Q. Right. But we've covered now the source of your knowledge of what happens to polypropylene when it cracks. That's Clave, and that's documents 18 and 19 in Deposition Exhibit 3?
  - A. Those are the studies that I'm aware of.
- Q. On page 7 of your report in the middle of the page, there's a paragraph that begins, While the addition of stabilizers to polypropylene. You reference a figure 2(a).
  - A. That should be figure 1(a). I think that's an error. I don't know that I have a figure 2 in this report.
    - Q. So figure 1(a) goes back to page 5?

31 (Pages 118 to 121)

#### Page 122 Page 124 1 A. That's right. 1 So what I would say is if you took 2 Q. All right. The last sentence of that 2 the entire suture and measured -- it depends on 3 paragraph begins, At this embrittlement stage, 3 what you're probing and measuring. If you're 4 the elongation of the polymer decreases 4 measuring the molecular weight of the entire 5 substantially. Does that mean the fiber itself 5 suture, because the surface layer doesn't 6 shrinks? 6 represent the entire volume, you may not see a 7 7 A. No. The elongation is the Y axis on difference. 8 this plot. So the percent elongation is the 8 But by actually probing that surface 9 longest distance you can stretch it before it 9 layer like they did in this experiment, you 10 10 breaks. So it starts off around 800 percent would see that it has a lower molecular weight. 11 elongation. You could stretch it out to eight 11 But if you measure the bulk molecular weight, 12 times its initial length. 12 you may not see it. 13 So then when it becomes embrittled 13 That's what I was saying is you would 14 even at very small strains, the material fails 14 use -- molecular weight measurements are very 15 15 effective and useful. It's just you have to because it's become embrittled. 16 Q. Which leads to adverse events after 16 make sure you're sampling the degraded region implantation such as extrusion and chronic pain of the polymer correctly. 17 17 Q. If you go back to page 5 of your 18 caused by sclerosis. What is sclerosis? 18 19 A. Sclerosis would be hardening of the 19 report --20 20 implant in the tissue. A. Right. 21 Q. This is the same phenomenon we talked 21 Q. -- you have more than a 20 percent 22 about a few minutes ago? 22 reduction in molecular weight before you have 23 A. Yes. 23 embrittlement, don't you? 24 A. Yes. That was a film, you know, so Q. Dr. Guelcher, if there's no reduction 24 Page 123 Page 125 in molecular weight, would you agree that 1 1 it's a different -- it's different than -- I 2 there's no degradation of the polypropylene? 2 mean, these experiments were specifically 3 MR. JACKSON: Object to the form. 3 designed to test this idea. So I don't know 4 A. Again, I think this is a more complex 4 that you would necessarily see the same thing 5 question. When you measure the molecular 5 in a suture. 6 weight, you're measuring the molecular weight 6 Q. Okay. You've not tested it in a 7 of the entire material. So if the degradation 7 suture? 8 is occurring at the surface, you may not see 8 A. No. I guess what I'm saying is 9 it. 9 molecular weight -- to clear up what I was 10 It's difficult to probe. So I guess 10 saying earlier, molecular weight is very 11 the way I want to answer that is if I go back 11 important. It's just sampling that degraded 12 to the -- if I go back to the Ethicon human 12 layer by molecular weight analysis can be very 13 implant results where they noted --13 difficult to do. That's why we like methods 14 Q. That's Tab 18? 14 like XPS because you can use smaller amounts. 15 A. I believe it's Tab 18. If I go back 15 MR. THOMAS: Let's go off the record 16 to that one, they mentioned the cracked 16 for a second. 17 surfaces were easily wiped off and deposited on 17 (A break was taken from 12:27 to 1:43 18 a KBR window for IR. The surface scrapings had 18 19 the handling consistency of a waxy snow. 19 Q. (By Mr. Thomas) Dr. Guelcher, has 20 Then they noted that the surface 20 Dr. Dunn submitted any invoices for your time 21 scrapings were melted at 147 and 156 degrees on 21 in this case yet? 22 a hot stage, and this is the melting range 22 A. I don't know if he's submitted 23 previously observed for oxidatively degraded 23 invoices to the attorneys. I've submitted 24 polypropylene. 24 invoices to him, but I don't know that he's

	Page 126		Page 128
1	submitted them to the attorneys.	1	No. 3. When did you review the documents in
2	Q. How many invoices have you submitted?	2	Exhibit No. 3?
3	A. I believe one.	3	A. Last week.
4	Q. Okay.	4	Q. Okay. And the documents in Exhibit
5	A. I can't remember.	5	No. 3 is your best effort at identifying all
6	Q. If you look at Exhibit No. 1, which	6	the documents upon which you rely for your
7	is your expert report in this case, how much	7	rebuttal report which is Exhibit No. 5 that I
8	time did you have in this case prior to the	8	got this morning; correct?
9	time that you completed Exhibit No. 1?	9	A. Right.
10	MR. JACKSON: Object to the form.	10	Q. All right. Now, other than reviewing
11	A. I don't remember.	11	the documents for Exhibit No. 2 and the
12	Q. (By Mr. Thomas) The time that you	12	documents for Exhibit No. 3, what other work
13	have in this case prior to the time that you	13	have you done in this case?
14	completed Exhibit No. 1 would be reflected in	14	A. Well, I wrote the reports.
15	your billing records?	15	Q. Right.
16	A. I believe it would.	16	A. I reviewed the documents. I
17	Q. Okay. From the time that you	17	Q. When you say you reviewed the
18	completed Exhibit No. 1, what additional work	18	documents, is your review limited to the
19	have you done in this matter since that time?	19	documents in Exhibits 2 and 3?
20	A. I reviewed the documents. I wrote	20	A. There were other documents I went
21	the rebuttal report. I met with the attorneys	21	through as well. They're all listed all the
22	and Dr. Dunn to discuss the documents.	22	reliance documents that are listed in the
23	Q. Now, the documents that you've	23	report. I mean, they're all
24	reviewed after Exhibit No. 1, what documents	24	Q. That's where I want to ask you about
	Page 127		Page 129
1	were those?	1	it. If you go to page 11 of Exhibit No. 1, it
2	A. Well, the ones in Exhibit No. 3, I	2	says in the second sentence, In addition to my
3	guess. Yeah, this one.	3	knowledge, skill, training, and experience as
4	Q. The documents that are in Exhibit		
5		4	an engineer, the following depositions of
i	No. 2 are the documents that go with your first	4 5	
6	No. 2 are the documents that go with your first report; correct?		an engineer, the following depositions of
		5	an engineer, the following depositions of Ethicon employees and the exhibits thereto were
6	report; correct?	5 6	an engineer, the following depositions of Ethicon employees and the exhibits thereto were supplied to me. And then there's a list of
6 7	report; correct?  A. Yes. I reviewed those again too.	5 6 7	an engineer, the following depositions of Ethicon employees and the exhibits thereto were supplied to me. And then there's a list of people.
6 7 8	report; correct?  A. Yes. I reviewed those again too.  Q. Did you review those before you did	5 6 7 8	an engineer, the following depositions of Ethicon employees and the exhibits thereto were supplied to me. And then there's a list of people.  Did you read all those depositions?
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33 (Pages 126 to 129)

	Page 130		Page 132
1	study.	1	Q. Do you know when trial is scheduled
2	Q. The next paragraph says, I've also	2	in this case?
3	considered the following material identified in	3	A. I don't.
4	Exhibit B.	4	Q. Compensation is listed at \$275 an
5	Again, there are documents in	5	hour for review and study, \$350 per hour for
6	Exhibit B that aren't in your two notebooks;	6	deposition and trial testimony time.
7	correct?	7	How much time have you billed
8	A. Yeah, I think so.	8	Dr. Dunn for, as of today?
9	Q. And is it fair to understand that to	9	A. I don't remember how many it's been.
10	the extent you identified documents that were	10	Q. Have you been paid yet?
11	important to your opinions, you put those in	11	A. I can't remember when I submitted the
12	your notebooks, Exhibits 2 and 3?	12	reports. I may have been paid something for
13	A. Right.	13	writing a report, but I can't remember when
14	Q. In addition, the following Rule 26	14	those invoices were submitted.
15	reports were supplied to me, and a list of	15	Q. Are you paid yourself \$275 an hour,
16	people. These reports were provided after we	16	or is that time that's billed to Dr. Dunn's
17	had reached my opinions in this case.	17	company and you're paid something different?
18	Did you review any of those Rule 26	18	A. So Dr. Dunn bills all the effort at
19	reports?	19	275 or 350 through his company, and he pays me
20	A. No, not much, I don't think.	20	200 as a subcontractor through his company. So
21	Q. There's nothing in those Rule 26	21	I'm not an employee, but I'm a subcontractor of
22	reports that have any bearing on the opinions	22	his company.
23	that you're giving today as far as you know?	23	Q. Okay. So you receive \$200 an hour
24	A. No.	24	whether it's review and study or whether it's
	Page 131		
			Page 133
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2	MR. JACKSON: Objection to form. Q. (By Mr. Thomas) Down in heading	2	deposition and trial time?  A. It's \$200 for review and study and
2	MR. JACKSON: Objection to form. Q. (By Mr. Thomas) Down in heading No. 5, it talks about exhibits which I plan to	2 3	deposition and trial time?  A. It's \$200 for review and study and 275 for deposition and trial testimony.
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	Page 134		Page 136
1	Q. Did you discuss your work on your	1	Q. Are they all AMS meshes?
2	initial report with Dr. Dunn as you were doing	2	A. I believe they are.
3	the work?	3	Q. And where did you obtain the meshes?
4	A. I believe so. I don't quite remember	4	A. From Dr. Iakovlev.
5	what we talked about prior to writing the	5	Q. Do you know where he obtained them?
6	report.	6	A. I'm not exactly sure. I mean, they
7	Q. When you wanted materials to review	7	came from the hospital, I believe, that treated
8	in connection with the work that you were doing	8	the patient. But I don't know exactly which
9	in this project, did you speak with Dr. Dunn or	9	hospital. I don't remember.
10	to counsel?	10	Q. Are you and Dr. Dunn in possession of
11	A. I spoke with Dr. Dunn. Dr. Dunn,	11	the explants now?
12	through his company, handles all those types of	12	A. I don't know. Dr. Bridget Rogers at
13	transfers with counsel.	13	Vanderbilt ran the XPS maybe a month ago. I
14	Q. Are you currently engaged in any	14	don't know who has them now, if we still have
15	projects with Dr. Dunn and any other expert in	15	them or if he sent them back.
16	this litigation that is a research project on	16	Q. Who handled the meshes when they were
17	meshes used in the pelvic floor?	17	here at Vanderbilt?
18	A. So are you talking expert witness in	18	A. I believe Dr. Rogers.
19	litigation, or are you talking about research	19	Q. Do you know how the explants were
20	projects?	20	received, in what form?
21	Q. Research projects.	21	A. They were received as dried fibers.
22	A. We are.	22	Q. Do you know who was responsible for
23	Q. And how many projects?	23	the preparation of the explanted mesh samples?
24	A. With Dr. Dunn, there's one.	24	A. Dr. Iakovlev.
	Page 135		Page 137
1	Q. And are there projects with other	1	Q. Did you have any do you and
2	Q. And are there projects with other experts?	2	Q. Did you have any do you and Dr. Dunn have any involvement in how those
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	Page 138		Page 140
1	Q. And what will the XPS hopefully show?	1	Q. Is that the full scope of the work
2	What will this test tell you about the	2	that you and Dr. Dunn are doing?
3	explanted meshes?	3	A. As of right now.
4	MR. JACKSON: Object to form.	4	Q. Do you have plans to do additional
5	A. Well, it would tell you whether	5	work?
6	there's oxygen bound with carbon on the	6	A. I don't know. We're still discussing
7	surface.	7	it.
8	Q. (By Mr. Thomas) Is it able to	8	Q. Who was involved in this project
9	quantify or just detect presence?	9	other than you and Dr. Dunn?
10	A. Quantify.	10	A. Dr. Iakovlev.
11	•	11	Q. Who is funding this project?
12	Q. And in what amounts or quantification	12	
13	would the oxygen bound to carbon be significant	13	<ul><li>A. We're discussing that right now.</li><li>Q. Is anybody funding it now?</li></ul>
14	in the analysis of oxidation of explanted mesh?	14	-
15	A. Any oxygen would be significant. As		
16	Fayolle teaches, it doesn't take much on the	15	litigation.
17	surface to catalyze the oxidation of the material.	16 17	Q. Does that mean you've received payment from counsel for the plaintiffs in the
18			AMS litigation?
	Oxygen shouldn't be there. It's a	18	_
19 20	hydrocarbon. So any bound oxygen in the material would have to be a result of	19 20	A. Dr. Rogers did for the XPS
21		21	experiments.
22	oxidation. So anything that we found would be	22	Q. Any other source of payments? Have you received any compensation for your work on
23	significant.  Q. What efforts were made to clean the	23	this project?
24	mesh prior to the XPS testing to remove any	24	A. Yes. I mean, it's billed, but I
24	mesh prior to the Ar3 testing to remove any	24	A. Tes. Tilleall, it's blilled, but I
	Page 139		Page 141
1	Page 139 other materials that didn't belong there?	1	Page 141 didn't actually do the XPS experiments. I've
1 2		1 2	
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	Page 142		Page 144
1	A. I don't.	1	A. It's a presubmission inquiry, so it's
2	Q. What is Dr. Dunn doing on this	2	basically an abstract of figures.
3	project?	3	Q. So there has been work conducted and
4	MR. JACKSON: Object to the form.	4	data collected so far?
5	A. Mostly consulting.	5	A. Yes.
6	Q. (By Mr. Thomas) What are you doing	6	Q. That's what I want to know. What
7	on this project?	7	kind of work have you done and data you've
8	A. I had some discussions with	8	collected for this project?
9	Dr. Iakovlev about staining for things like	9	A. Well, so Dr. Iakovlev did the data
10	myeloperoxidase to show evidence of active	10	collection. There's histological staining,
11	macrophages at the site, similar to what I've	11	staining of histological sections. There's
12	done with the other materials I've worked with.	12	microscopy showing the presence of a degraded
13	Q. What would the staining of the meshes	13	layer on the surface.
14	to show active macrophages at the site show	14	Q. Is that light microscopy or SCM?
15	you?	15	A. Both, polarized light microscopy,
16	A. It would show that there's secretion	16	SCM. There's another type of imaging technique
17	of myeloperoxidase, which is an enzyme that is	17	he used as well. It's all imaging in
18	involved in these reactive oxygen species. So	18	histology.
19	it would show the presence of that enzyme and	19	Q. What is the question that this paper
20	provide evidence that macrophages are at the	20	seeks to answer?
21	material surface secreting these reactive	21	MR. JACKSON: Object to the form,
22	oxygen species that can promote oxidation of	22	asked and answered.
23	the polymer.	23	A. Well, the paper is directed toward
24	Q. What's the status of the work that	24	providing evidence that polypropylene degrades
			providing evidence and posypropyrene degrades
		1	
	Page 143		Page 145
1	Page 143 you're doing with Dr. Iakovlev on these	1	Page 145 in vivo by an oxidative mechanism.
1 2		1 2	in vivo by an oxidative mechanism.  Q. (By Mr. Thomas) And who has funded
	you're doing with Dr. Iakovlev on these		in vivo by an oxidative mechanism.
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Page 146 Page 148 1 surface degradation. Dr. Iakovlev is a 1 on another one. But that's what I've got 2 pathologist, so my contribution is more on the 2 at this point. 3 3 material science, chemistry, the things Q. (By Mr. Thomas) Let's go back to 4 described in my report. 4 your original report, page 8, the paragraph 5 Q. The work that you and Dr. Dunn are 5 that begins, Finally with respect to the idea, 6 doing with the AMS polypropylene explants where 6 the next sentence reads, These stresses cannot 7 7 you're analyzing the surface of the material by only act as catalysts for oxidative 8 8 XPS, are there plans to publish that research? degradation, they can alter the properties of 9 A. We would like to publish it, but 9 the mesh itself. 10 10 we're not as far along as Dr. Iakovlev is. What properties of the mesh are 11 Q. What laboratory is doing the imaging 11 changed by the stresses that you discuss in 12 that Dr. Iakovlev is doing for the 12 that paragraph? 13 polypropylene explant materials? 13 A. I'm just going to read it again. 14 A. I don't know where he's doing it. I 14 Q. Sure. 15 A. I think what I'm saying here is that 15 presume he's doing it at his university in 16 16 the antioxidants basically guard against --Toronto. 17 17 Q. Is any of the work on the explanted antioxidants are designed to protect against 18 oxidation. So mechanical stresses on the 18 meshes in the polypropylene explant study by 19 Dr. Iakovlev being done at Vanderbilt? 19 material can sort of exacerbate these effects. 20 20 Mechanical loading of the mesh pelvic A. No. 21 floor environment is different, say, than the 21 Q. And the XPS work and the work with 22 2.2 Dr. Dunn has been done by Dr. Rogers at suture. That can cause changes in the 23 23 degradation and response of the material. Vanderbilt? 24 That's what I'm really trying to say there. 24 A. Yes, that's right. Page 147 Page 149 1 1 Q. Are you involved in any research or Q. Help me out a little bit. I don't 2 projects to identify a better material for use 2 really understand that. They can alter the 3 as a medical device in the pelvic floor? 3 properties of the mesh. What properties of the 4 4 mesh can be altered? A. No. 5 5 O. Have you done any work in this A. Strength. It's elongation. These 6 litigation about a suitable alternative device 6 changes in the polypropylene are happening over 7 for the treatment of stress urinary 7 time. They can change as mechanical properties 8 8 incontinence that is equally safe and effective which is toughness, embrittleness, these things 9 as the Ethicon TVT device? 9 we've been talking about. 10 MR. JACKSON: Objection to form. 10 Q. Does it include tensile strength? 11 A. Again, I was -- my report, my intent 11 A. Yeah. Tensile strength would be 12 was to review the in vivo performance of 12 another mechanical property that could change 13 polypropylene and not look at alternative 13 over time due to oxidative changes. 14 14 Q. Okay. So you have tensile strength, devices. 15 MR. THOMAS: Am I going to get the 15 you have elongation, you have toughness. What 16 time sheets today? 16 other physical properties of the mesh can be 17 17 altered by oxidative degradation? MR. JACKSON: I'm actually waiting on 18 a response to my e-mail. But the last I 18 A. I think basically it's the 19 heard is that these were included in our 19 embrittlement -- it's going to become more 20 objections to the request for production 20 brittle, less tough. The strength could 21 attached to the deposition. 21 change. Those are the -- that's what I think 22 MR. THOMAS: Really? 22 of when I think of embrittlement. 23 MR. JACKSON: That's the last 23 Q. Are those the results of the 24 response I got, but I am actually waiting 24 oxidative degradation that you discuss in this

38 (Pages 146 to 149)

Page 150 Page 152 1 1 in the lab. paper? 2 A. Yes. 2 Q. The reason why you keep MSDS sheets 3 3 Q. It's those changes in the physical for materials in the lab is in the event 4 properties that you just identified that 4 somebody in the lab is exposed to that material 5 compromise the ability of the mesh to perform 5 while handling it; correct? 6 its function in the body; is that fair? 6 MR. JACKSON: Objection to form. 7 7 A. Yes. I believe that those changes Q. (By Mr. Thomas) Is that true? 8 in -- the changes in the composition of the 8 A. Yeah. That's why we have them. 9 9 Q. The reason why you have the material polymer due to the oxidation combined with 10 mechanical forces in the environment of the 10 safety data sheets is not to determine what the 11 pelvic floor can cause the mesh to change over 11 clinical impact of implanting those materials 12 12 may be in the human body? 13 Q. And it's those changes in strength, 13 A. I think it's something that should be 14 elongation, toughness, embrittlement that you 14 considered. I mean, if it says on the MSDS 15 conclude compromise the ability of the mesh to 15 it's incompatible with strong oxidizers and you 16 perform its function in the pelvic floor? 16 know that part of the cellular response is 17 A. I think that's part of it. 17 materials that secrete strong oxidizers, that's 18 Q. What else is there? 18 something that should be considered. 19 A. I think as I've been saying in the 19 Q. In your judgment, what does a strong 20 20 report, it's really the embrittlement of the oxidizer mean? What's relevant in terms of 21 mesh is what's causing it to change over time 21 strong for purposes of degradation to and lead to extrusion and these types of 22 22 polypropylene mesh? 23 problems. 23 A. Well, molecular oxygen will oxidize 24 24 Q. Anything else? polypropylene at elevated temperatures. Page 151 Page 153 1 A. I think that's . . . 1 Stronger oxidizers such as hypochloric acid and 2 Q. Let's go to page 10 of your report, 2 peroxides listed here are stronger oxidizing 3 3 please. When you're considering the use of a agents than chlorine. biomaterial for implantation in a human body, 4 These are all stronger oxidizing 4 5 do you consult that material safety data sheet? 5 agents than molecular oxygen. That's what I'm 6 6 A. That's one piece of information. The referring to when I say reactive oxygen 7 materials that I'm making, we don't -- they're 7 species. 8 experimental. So we don't have material safety 8 Q. What strength chlorine is required to 9 data sheets. 9 degrade polypropylene that has antioxidants 10 10 But for an established material like added to it? 11 MR. JACKSON: Objection to form. polypropylene, that's one factor I would look 11 A. I mean, that's the problem with 12 at, is what the MSDS is saying about the 12 13 designing these implants for permanent 13 14 Q. Is it normally part of your business 14 implantation. It's very difficult to predict 15 when you start working with a material that's 15 what dose of antioxidant is going to be 16 going to be implanted in the human body, is it 16 required to protect every patient from this 17 your practice to go to the material safety data 17 oxidation. 18 sheet to see what it says about that material? 18 Q. (By Mr. Thomas) Do you have an 19 MR. JACKSON: Object to the form. 19 opinion about how much chlorine would be 20 A. That's typically what we do whether 20 required to degrade Prolene polypropylene 21 it's in the human body or not. If we're using 21 that's been treated with an antioxidant 22 it in the laboratory if there's a possibility 22 package? 23 of someone being exposed to it, we keep a file 23 MR. JACKSON: Objection to form. 24 of the MSDSs for all the materials we're using 24 A. I think you can't just parse out.

	Page 154		Page 156
1	These are reactive oxygen species. There's a	1	THE WITNESS: Yeah. It's in my
2	number of different molecules that are secreted	2	paper.
3	by inflammatory cells that have been shown in	3	MR. JACKSON: It's referenced as
4	Ethicon studies and in published papers to	4	footnote 9.
5	cause surface degradation of polypropylene.	5	THE WITNESS: Yeah. It says
6	So we know that what the cells	6	"document not available."
7	secrete is enough to oxidize the propylene.	7	A. I'm just checking Anderson's review
8	It's been observed in several studies.	8	to see if he tells what it is in here as well.
9	Q. My question is a little different.	9	Well, I don't remember the exact
10	Do you have an opinion as to the amount of any	10	composition of the solution. But he's
11	of these materials, strong oxidizers such as	11	published a number of papers, and we've used it
12	chlorine, peroxides, etc., that are necessary	12	as well. It's a fluid that can be used to
13	and sufficient to cause the oxidation of	13	simulate the macrophage pocket in vitro.
14	Prolene polypropylene?	14	Q. (By Mr. Thomas) That's in the
15	MR. JACKSON: Objection to form.	15	context of the polypropylene?
16	A. My answer would be that macrophages	16	A. No. Other people have cited this as
17	secrete sufficient amounts of these molecules.	17	well. It's an in vitro model for oxidative
18	I mean, we know this because it's been	18	degradation.
19	observed.	19	Q. You've talked about Dr. Anderson many
20	I don't know that anybody has	20	times. The one study that we've marked is
21	measured or I don't know how you would measure	21	it cited in your paper?
22	the exact concentration. It's really	22	A. It's No. 8.
23	irrelevant. It's not being done outside the	23	Q. Is it Exhibit 8?
24	body. It's being you know, Dr. Anderson has	24	A. I don't know what the exhibit is.
1	Page 155		Page 157
1	published this solution that's been shown to	1	It's No. 6.
2	simulate the composition of that macrophage		
		2	Q. Have you worked with Dr. Anderson
3	pocket.	3	before?
4	pocket.  But, again, it's a very complex	3 4	before?  A. I've not worked with him. I know him
4 5	pocket.  But, again, it's a very complex reaction. There's a number of species	3 4 5	before?  A. I've not worked with him. I know him professionally.
4 5 6	pocket.  But, again, it's a very complex reaction. There's a number of species involved.	3 4 5 6	before?  A. I've not worked with him. I know him professionally.  Q. Okay. So when you cite to
4 5 6 7	pocket.  But, again, it's a very complex reaction. There's a number of species involved.  Q. One of the things you would like to	3 4 5 6 7	before?  A. I've not worked with him. I know him professionally.  Q. Okay. So when you cite to Dr. Anderson, it's based on your knowledge of
4 5 6 7 8	pocket.  But, again, it's a very complex reaction. There's a number of species involved.  Q. One of the things you would like to know is the amount of oxidizers that may	3 4 5 6 7 8	before?  A. I've not worked with him. I know him professionally.  Q. Okay. So when you cite to Dr. Anderson, it's based on your knowledge of his studies and conversations that you've had
4 5 6 7 8 9	pocket.  But, again, it's a very complex reaction. There's a number of species involved.  Q. One of the things you would like to know is the amount of oxidizers that may compromise polypropylene so that you can modify	3 4 5 6 7 8	before?  A. I've not worked with him. I know him professionally.  Q. Okay. So when you cite to Dr. Anderson, it's based on your knowledge of his studies and conversations that you've had with him personally as opposed to work that
4 5 6 7 8 9	pocket.  But, again, it's a very complex reaction. There's a number of species involved.  Q. One of the things you would like to know is the amount of oxidizers that may compromise polypropylene so that you can modify your additive package to resist that oxidation;	3 4 5 6 7 8 9	before?  A. I've not worked with him. I know him professionally.  Q. Okay. So when you cite to Dr. Anderson, it's based on your knowledge of his studies and conversations that you've had with him personally as opposed to work that you've done with him on studies?
4 5 6 7 8 9 10	pocket.  But, again, it's a very complex reaction. There's a number of species involved.  Q. One of the things you would like to know is the amount of oxidizers that may compromise polypropylene so that you can modify your additive package to resist that oxidation; fair?	3 4 5 6 7 8 9 10	before?  A. I've not worked with him. I know him professionally.  Q. Okay. So when you cite to Dr. Anderson, it's based on your knowledge of his studies and conversations that you've had with him personally as opposed to work that you've done with him on studies?  A. It's mostly through citations. He's
4 5 6 7 8 9 10 11 12	pocket.  But, again, it's a very complex reaction. There's a number of species involved.  Q. One of the things you would like to know is the amount of oxidizers that may compromise polypropylene so that you can modify your additive package to resist that oxidation; fair?  MR. JACKSON: Object to the form.	3 4 5 6 7 8 9 10 11 12	before?  A. I've not worked with him. I know him professionally.  Q. Okay. So when you cite to Dr. Anderson, it's based on your knowledge of his studies and conversations that you've had with him personally as opposed to work that you've done with him on studies?  A. It's mostly through citations. He's very well known in this area of foreign body
4 5 6 7 8 9 10 11 12 13	pocket.  But, again, it's a very complex reaction. There's a number of species involved.  Q. One of the things you would like to know is the amount of oxidizers that may compromise polypropylene so that you can modify your additive package to resist that oxidation; fair?  MR. JACKSON: Object to the form.  A. Dr. Anderson has come the closest to	3 4 5 6 7 8 9 10 11 12 13	before?  A. I've not worked with him. I know him professionally.  Q. Okay. So when you cite to Dr. Anderson, it's based on your knowledge of his studies and conversations that you've had with him personally as opposed to work that you've done with him on studies?  A. It's mostly through citations. He's very well known in this area of foreign body response. That's his area of expertise. He's
4 5 6 7 8 9 10 11 12 13 14	pocket.  But, again, it's a very complex reaction. There's a number of species involved.  Q. One of the things you would like to know is the amount of oxidizers that may compromise polypropylene so that you can modify your additive package to resist that oxidation; fair?  MR. JACKSON: Object to the form.  A. Dr. Anderson has come the closest to describing it as a mixture of cobalt and	3 4 5 6 7 8 9 10 11 12 13 14	before?  A. I've not worked with him. I know him professionally.  Q. Okay. So when you cite to Dr. Anderson, it's based on your knowledge of his studies and conversations that you've had with him personally as opposed to work that you've done with him on studies?  A. It's mostly through citations. He's very well known in this area of foreign body response. That's his area of expertise. He's very well known in that field.
4 5 6 7 8 9 10 11 12 13 14	pocket.  But, again, it's a very complex reaction. There's a number of species involved.  Q. One of the things you would like to know is the amount of oxidizers that may compromise polypropylene so that you can modify your additive package to resist that oxidation; fair?  MR. JACKSON: Object to the form.  A. Dr. Anderson has come the closest to describing it as a mixture of cobalt and peroxide that simulates I've published a few	3 4 5 6 7 8 9 10 11 12 13 14 15	before?  A. I've not worked with him. I know him professionally.  Q. Okay. So when you cite to Dr. Anderson, it's based on your knowledge of his studies and conversations that you've had with him personally as opposed to work that you've done with him on studies?  A. It's mostly through citations. He's very well known in this area of foreign body response. That's his area of expertise. He's very well known in that field.  Q. Now, we talked about Exhibit No. 6
4 5 6 7 8 9 10 11 12 13 14 15	pocket.  But, again, it's a very complex reaction. There's a number of species involved.  Q. One of the things you would like to know is the amount of oxidizers that may compromise polypropylene so that you can modify your additive package to resist that oxidation; fair?  MR. JACKSON: Object to the form.  A. Dr. Anderson has come the closest to describing it as a mixture of cobalt and peroxide that simulates I've published a few papers on this.	3 4 5 6 7 8 9 10 11 12 13 14 15	before?  A. I've not worked with him. I know him professionally.  Q. Okay. So when you cite to Dr. Anderson, it's based on your knowledge of his studies and conversations that you've had with him personally as opposed to work that you've done with him on studies?  A. It's mostly through citations. He's very well known in this area of foreign body response. That's his area of expertise. He's very well known in that field.  Q. Now, we talked about Exhibit No. 6 earlier, and I understood that the reason why
4 5 6 7 8 9 10 11 12 13 14 15 16	pocket.  But, again, it's a very complex reaction. There's a number of species involved.  Q. One of the things you would like to know is the amount of oxidizers that may compromise polypropylene so that you can modify your additive package to resist that oxidation; fair?  MR. JACKSON: Object to the form.  A. Dr. Anderson has come the closest to describing it as a mixture of cobalt and peroxide that simulates I've published a few papers on this.  Q. (By Mr. Thomas) You have or he has?	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	before?  A. I've not worked with him. I know him professionally.  Q. Okay. So when you cite to Dr. Anderson, it's based on your knowledge of his studies and conversations that you've had with him personally as opposed to work that you've done with him on studies?  A. It's mostly through citations. He's very well known in this area of foreign body response. That's his area of expertise. He's very well known in that field.  Q. Now, we talked about Exhibit No. 6 earlier, and I understood that the reason why you cited that paper was for discussion of the
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	pocket.  But, again, it's a very complex reaction. There's a number of species involved.  Q. One of the things you would like to know is the amount of oxidizers that may compromise polypropylene so that you can modify your additive package to resist that oxidation; fair?  MR. JACKSON: Object to the form.  A. Dr. Anderson has come the closest to describing it as a mixture of cobalt and peroxide that simulates I've published a few papers on this.  Q. (By Mr. Thomas) You have or he has?  A. Well, I have. I don't know if my	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	before?  A. I've not worked with him. I know him professionally.  Q. Okay. So when you cite to Dr. Anderson, it's based on your knowledge of his studies and conversations that you've had with him personally as opposed to work that you've done with him on studies?  A. It's mostly through citations. He's very well known in this area of foreign body response. That's his area of expertise. He's very well known in that field.  Q. Now, we talked about Exhibit No. 6 earlier, and I understood that the reason why you cited that paper was for discussion of the foreign body response to implanted materials;
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	pocket.  But, again, it's a very complex reaction. There's a number of species involved.  Q. One of the things you would like to know is the amount of oxidizers that may compromise polypropylene so that you can modify your additive package to resist that oxidation; fair?  MR. JACKSON: Object to the form.  A. Dr. Anderson has come the closest to describing it as a mixture of cobalt and peroxide that simulates I've published a few papers on this.  Q. (By Mr. Thomas) You have or he has?  A. Well, I have. I don't know if my paper is in here or not. It may not be.	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	before?  A. I've not worked with him. I know him professionally.  Q. Okay. So when you cite to Dr. Anderson, it's based on your knowledge of his studies and conversations that you've had with him personally as opposed to work that you've done with him on studies?  A. It's mostly through citations. He's very well known in this area of foreign body response. That's his area of expertise. He's very well known in that field.  Q. Now, we talked about Exhibit No. 6 earlier, and I understood that the reason why you cited that paper was for discussion of the foreign body response to implanted materials; correct?
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	pocket.  But, again, it's a very complex reaction. There's a number of species involved.  Q. One of the things you would like to know is the amount of oxidizers that may compromise polypropylene so that you can modify your additive package to resist that oxidation; fair?  MR. JACKSON: Object to the form.  A. Dr. Anderson has come the closest to describing it as a mixture of cobalt and peroxide that simulates I've published a few papers on this.  Q. (By Mr. Thomas) You have or he has?  A. Well, I have. I don't know if my paper is in here or not. It may not be.  Dr. Anderson is the first to publish it. It's	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	before?  A. I've not worked with him. I know him professionally.  Q. Okay. So when you cite to Dr. Anderson, it's based on your knowledge of his studies and conversations that you've had with him personally as opposed to work that you've done with him on studies?  A. It's mostly through citations. He's very well known in this area of foreign body response. That's his area of expertise. He's very well known in that field.  Q. Now, we talked about Exhibit No. 6 earlier, and I understood that the reason why you cited that paper was for discussion of the foreign body response to implanted materials; correct?  A. Yes.
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	pocket.  But, again, it's a very complex reaction. There's a number of species involved.  Q. One of the things you would like to know is the amount of oxidizers that may compromise polypropylene so that you can modify your additive package to resist that oxidation; fair?  MR. JACKSON: Object to the form.  A. Dr. Anderson has come the closest to describing it as a mixture of cobalt and peroxide that simulates I've published a few papers on this.  Q. (By Mr. Thomas) You have or he has?  A. Well, I have. I don't know if my paper is in here or not. It may not be.  Dr. Anderson is the first to publish it. It's not in here. Let's see if it's in the other	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	before?  A. I've not worked with him. I know him professionally.  Q. Okay. So when you cite to Dr. Anderson, it's based on your knowledge of his studies and conversations that you've had with him personally as opposed to work that you've done with him on studies?  A. It's mostly through citations. He's very well known in this area of foreign body response. That's his area of expertise. He's very well known in that field.  Q. Now, we talked about Exhibit No. 6 earlier, and I understood that the reason why you cited that paper was for discussion of the foreign body response to implanted materials; correct?  A. Yes.  Q. What specifically is it about the
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	pocket.  But, again, it's a very complex reaction. There's a number of species involved.  Q. One of the things you would like to know is the amount of oxidizers that may compromise polypropylene so that you can modify your additive package to resist that oxidation; fair?  MR. JACKSON: Object to the form.  A. Dr. Anderson has come the closest to describing it as a mixture of cobalt and peroxide that simulates I've published a few papers on this.  Q. (By Mr. Thomas) You have or he has?  A. Well, I have. I don't know if my paper is in here or not. It may not be.  Dr. Anderson is the first to publish it. It's not in here. Let's see if it's in the other one.	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	before?  A. I've not worked with him. I know him professionally.  Q. Okay. So when you cite to Dr. Anderson, it's based on your knowledge of his studies and conversations that you've had with him personally as opposed to work that you've done with him on studies?  A. It's mostly through citations. He's very well known in this area of foreign body response. That's his area of expertise. He's very well known in that field.  Q. Now, we talked about Exhibit No. 6 earlier, and I understood that the reason why you cited that paper was for discussion of the foreign body response to implanted materials; correct?  A. Yes.  Q. What specifically is it about the Anderson paper that's important to your
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	pocket.  But, again, it's a very complex reaction. There's a number of species involved.  Q. One of the things you would like to know is the amount of oxidizers that may compromise polypropylene so that you can modify your additive package to resist that oxidation; fair?  MR. JACKSON: Object to the form.  A. Dr. Anderson has come the closest to describing it as a mixture of cobalt and peroxide that simulates I've published a few papers on this.  Q. (By Mr. Thomas) You have or he has?  A. Well, I have. I don't know if my paper is in here or not. It may not be.  Dr. Anderson is the first to publish it. It's not in here. Let's see if it's in the other	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	before?  A. I've not worked with him. I know him professionally.  Q. Okay. So when you cite to Dr. Anderson, it's based on your knowledge of his studies and conversations that you've had with him personally as opposed to work that you've done with him on studies?  A. It's mostly through citations. He's very well known in this area of foreign body response. That's his area of expertise. He's very well known in that field.  Q. Now, we talked about Exhibit No. 6 earlier, and I understood that the reason why you cited that paper was for discussion of the foreign body response to implanted materials; correct?  A. Yes.  Q. What specifically is it about the

Page 158 Page 160 1 researchers as well. This is, I think, a 1 Q. It's the paragraph that begins "these 2 particularly well written concise review 2 studies." 3 summarizing his 30 years of work in this area. 3 A. Oh. 4 So it's -- I would say that he's a key thought 4 Q. The paragraph ends with, The chemical 5 leader in the field, and this is a very nicely 5 and molecular composition of the primary 6 written paper and it's useful for citing. 6 structure of the polyurethane polymer is known 7 7 Q. Let's go to 2.4 of Exhibit 6 which is to modulate or inhibit the process of 8 the Anderson paper. 8 environmental stress cracking and degradation. 9 9 And that's by adding these antioxidants; A. Okay. 10 10 Q. And the heading is Consequences of correct? 11 Foreign Body Giant Cell Formation. 11 A. No. That's not what he's saying at A. Right. 12 12 all. I think you're misreading this paragraph. So he says, These studies identify 13 Q. Right in the middle of that 13 the importance of the use of antioxidants to 14 paragraph, it says, For example, additional 14 15 polymers such as polypropylene used in 15 inhibit the oxidation process. Okay. So he's 16 artificial joints or polypropylene used as a 16 saying that people use it. suture material may undergo surface oxidation 17 17 Then he says, The persistence of the 18 by the ROIs. 18 foreign body reaction and the fact that it is 19 A. Yes. 19 present at the interface between the tissue and 20 20 Q. Medical devices and prostheses the device for the lifetime suggests that the 21 composed of addition polymers usually contain 21 oxidation process is continuous albeit at low 22 small amounts of antioxidants to inhibit this 22 levels. In general, chemical degradation and 23 oxidative processes. Do you see that? 23 physical damage in pacemaker leads most 24 24 A. Yes. probably have a synergistic effect on the Page 159 Page 161 1 Q. Has Dr. Anderson, to your knowledge, 1 failure of the insulation. 2 ever written that adding small amounts of 2 What he's saying in the last 3 3 antioxidants to inhibit this oxidative process paragraph is -- this is what I was talking is not sufficient to protect against the 4 about earlier. When he says the chemical and 4 5 5 degradation of polypropylene? molecular composition of the primary structure, A. I don't think he's saying here that 6 "primary structure" refers to the backbone of 6 7 it works or doesn't work. I just think he's 7 the polymer. 8 saying that this is what people do. 8 So a polyether urethane is known to 9 Q. My question is, are you aware of him 9 be very sensitive to oxidative degradation and 10 writing anywhere that the use of antioxidants 10 its consequent environmental stress cracking. doesn't work? 11 Polycarbonates or polysiloxane urethanes are 11 12 12 less sensitive. A. Again, he's not saying it works here 13 either. He's not saying it works or doesn't 13 So he's saying that the structure of 14 the urethane backbone, whether it's a polyether 14 work. 15 Q. If you go to the next page under 15 or polycarbonate in the polyurethane backbone is a contributing factor to this. He's not 16 figure 3, it says again that these studies 16 17 clearly identify the importance of the use of 17 talking about antioxidants there. 18 antioxidants in these polymers to inhibit the 18 Q. Is it fair to understand that you 19 oxidation process that occurs with the foreign 19 consider Dr. Anderson to be one of the leading 20 body reaction. 20 authorities in understanding the extent to 21 A. It says that in the text? Where does 21 which a foreign body reaction to biomaterials 22 it say --22 may impact oxidation?

41 (Pages 158 to 161)

A. I wouldn't say it that way. I would

say that Dr. Anderson spent a very long career

23

24

23

24

Q. It's under "device failure."

A. Yeah. Which paragraph?

```
Page 162
                                                                                                       Page 164
 1
        studying the response to the body through the
                                                              1
                                                                     about -- what I'm saying is, I'm not seeing any
 2
        foreign body reaction to implanted
                                                              2
                                                                     evidence here even in this presentation --
                                                              3
 3
        biomaterials. That's what this paper is
                                                                     they're talking about oxidation, and there's
 4
        talking about.
                                                              4
                                                                     really nothing here that suggests that these
 5
           Q. Have you ever had discussions with
                                                              5
                                                                     studies, looking at a dose response, how much
                                                              6
 6
        Dr. Anderson about whether antioxidants added
                                                                     do you have to dose the polypropylene to
 7
                                                              7
                                                                     protect it from oxidation?
        to polypropylene can sufficiently inhibit
 8
        oxidation of the polypropylene to allow the
                                                              8
                                                                           There's no evidence that this was
 9
        medical device to perform its intended
                                                              9
                                                                     looked at after this document in 1987. We
10
                                                             10
        function?
                                                                     couldn't find anything.
11
          A. I've not discussed that with
                                                             11
                                                                        Q. Did you ask anybody?
12
                                                                        A. We did. Well, Dr. Dunn, like I said,
        Dr. Anderson, but he's not saying that in this
                                                             12
                                                                     we talked about it. He talked with the
13
        statement. He's saying you can add
                                                             13
        antioxidants to try to help it, but the problem
14
                                                             14
                                                                     attorneys requesting, but I don't think these
15
        is that reaction is never going to stop. So
                                                             15
                                                                     documents could be found.
16
        how do you know how much to add?
                                                             16
                                                                        Q. Okay.
17
                                                             17
              Ethicon's own data showed that when
                                                                        A. That's what I know. So the only
                                                                     thing that I know about it is what's in these
18
        they add antioxidants, it's depleted after
                                                             18
19
        seven or eight years. So it didn't totally
                                                             19
                                                                     memos and these presentations where basically
20
                                                             20
                                                                     they're recognizing that there's oxidative
21
          Q. That's in that one study we talked
                                                             21
                                                                     degradation.
22
                                                             22
                                                                           But there's really no discussion of,
        about?
23
          A. Yeah. And I haven't seen any other
                                                             23
                                                                     Hey, let's do a dose response study. There's
                                                                     e-mails that say should we look at this. And,
24
        studies -- in one of the memos, they said that
                                                             24
                                          Page 163
                                                                                                       Page 165
                                                              1
 1
        they were looking at this. What reference is
                                                                     again, there's no evidence that I've seen that
 2
        that?
                                                              2
                                                                     it's being looked at.
 3
                                                              3
           Q. It was 18, 19, and 20.
                                                                           I guess I'm just saying it's unknown
           A. I think it was No. 20. They said --
                                                              4
                                                                     and, to my knowledge, it's not been looked at.
 4
                                                              5
                                                                       Q. Did you ask to see all of the
 5
        there's a memo, a follow-up to -- I think this
        was a -- well, the meeting minutes from the
                                                              6
                                                                     degradation work that Ethicon has in its files
 6
 7
                                                              7
                                                                     related to polypropylene?
        Prolene explants.
 8
                                                              8
               And, basically, it's summarizing
                                                                       A. I believe that Dr. Dunn did. I even
 9
        those human explants that I was talking about
                                                              9
                                                                     think Dr. Burkley was asked -- and I don't know
10
        earlier. And then there's a point on here at
                                                             10
                                                                     if I have that deposition in front of me.
        the top of page 2, it says, Mr. Burkley is
                                                             11
                                                                           But I believe that in Dr. Burkley's
11
12
        planning to look at the remaining dry explants
                                                             12
                                                                     deposition, he really was talking about the dog
13
        by IOR. He will also try to see the
                                                             13
                                                                     study. To our knowledge, there weren't other
                                                             14
        relationship between the amount of stabilizers
                                                                     studies.
14
15
        added to the polymer and degradation and
                                                             15
                                                                           (Exhibit 10 was marked.)
16
        cracking.
                                                             16
                                                                       Q. (By Mr. Thomas) Let me show you
17
                                                             17
                                                                     what's been marked as deposition Exhibit
               You know, we never -- we couldn't
18
        find anything further on that. In a number of
                                                             18
                                                                     No. 10. Deposition Exhibit 10 is a letter from
19
        these presentations that I have also from
                                                             19
                                                                     me to counsel in this case enclosing a list of
20
        Ethicon -- I can pull some of these up. This
                                                             20
                                                                     studies about which Ethicon testified at what's
21
        would be --
                                                             21
                                                                     known as a Rule 30(b)(6) deposition on various
22
           Q. That's your rebuttal report. I'm not
                                                             22
                                                                     studies that were conducted by Ethicon over the
23
                                                            23
        there yet.
```

42 (Pages 162 to 165)

And if you look at page 3 of Exhibit

24

24

A. I know. But you're asking me

	Page 166		Page 168
1	No. 10, there is a topic known as	1	CERTIFICATE OF COURT REPORTER
2	"degradation."	2	I, Marilyn Morgan, Licensed Court
3	A. Uh-huh.	3	Reporter and Notary Public for the State of
4	Q. And I take it that other than the dog	4	Tennessee, do certify that the above deposition
5	study, you've not seen any of these degradation	5	was reported by me and that the foregoing
6	studies where Ethicon has looked at to the	6	transcript is a true and accurate record to the
7	extent to which these the Ethicon	7 8	best of my knowledge, skills, and ability.
8	polypropylene degrades in vivo?	9	I further certify that I am not an employee of counsel or any of the parties, nor
9	MR. JACKSON: Objection to form.	10	a relative or employee of any attorney or
10	A. I haven't seen these studies.	11	counsel connected with the action, nor
11	Q. (By Mr. Thomas) Okay.	12	financially interested in the action.
12	A. This is just a list of	13	I further certify that I am duly
13	Q. They're available.	14	licensed by the Tennessee Board of Court
14	MR. THOMAS: Let's go off the record,	15	Reporting as a Licensed Court Reporter as
15	please.	16	evidenced by the LCR number and expiration date
16	(A break was taken from 2:41 p.m.	17	following my name below.
17	until 3:09.)	18	Subscribed and sworn to before me when
18	MR. THOMAS: While at recess, I've	19	taken, this 25th day of March, 2014.
19	had a number of conversations with counsel	20 21	
20	for the plaintiff about the unavailability		MARILYN MORGAN, LCR #235
21	of the time records that are the subject of	22	Expiration Date: 6/30/14
22	the deposition as well as the late service		Notary Public, State of Tennessee
23	of the rebuttal report and the anticipated	23	Commission expires: 6/18/17
24	production of a rebuttal report for Dr. Dunn	24	·
	Page 167		
1			3
	ribaga damagitian ig gabadulad fan tamamari	1	INCTRICTIONS TO WITNESS
	whose deposition is scheduled for tomorrow.	1	INSTRUCTIONS TO WITNESS
2	Counsel and I have agreed that we	2	
2	Counsel and I have agreed that we will stop the deposition of Dr. Guelcher	2 3	Please read your deposition
2 3 4	Counsel and I have agreed that we will stop the deposition of Dr. Guelcher today to resume at a later date; at which	2 3 4	Please read your deposition over carefully and make any necessary
2 3 4 5	Counsel and I have agreed that we will stop the deposition of Dr. Guelcher today to resume at a later date; at which point, I will be able to inquire about the	2 3 4 5	Please read your deposition over carefully and make any necessary corrections. You should state the reason
2 3 4	Counsel and I have agreed that we will stop the deposition of Dr. Guelcher today to resume at a later date; at which point, I will be able to inquire about the billing records which will be produced as	2 3 4 5 6	Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata
2 3 4 5 6 7	Counsel and I have agreed that we will stop the deposition of Dr. Guelcher today to resume at a later date; at which point, I will be able to inquire about the billing records which will be produced as well as the scope of the rebuttal report.	2 3 4 5 6 7	Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made.
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	Page 170	
1		
2	ERRATA	
3	PAGE LINE CHANGE	
5 6	REASON:	
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11 12	REASON:	
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21 22	REASON:	
23 24	REASON:	
	Page 171	
1	ACKNOWLEDGMENT OF DEPONENT	
2	I,, do hereby certify that I have read the	
3	foregoing pages, and that the same	
4	is a correct transcription of the answers given by me to the questions therein	
5	propounded, except for the corrections or	
6 7	changes in form or substance, if any, noted in the attached Errata Sheet.	
8	SCOTT A. GUELCHER, PH.D. DATE	
9 10		
11 12		
13		
14	Subscribed and sworn	
15	to before me this day of, 20	
16		
17 18	My commission expires:	
	Notary Public	
19 20		
21 22		
23 24		
44		

44 (Pages 170 to 171)